United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

DEC 17 2002

Dr. Frits H. Pluimers
Chief Veterinary Officer
Ministry of Agric., Nature Management and Fisheries
Room 4205
Post Office Box 20401
2500 EK The Hague
The Netherlands

Dear Dr. Pluimers:

The Food Safety and Inspection Service conducted an on-site audit of the Netherlands' meat inspection system from June 5 through July 1, 2002. Enclosed is a copy of the final audit report. Comments by the Netherlands on the draft final audit report have been included as an attachment to the enclosed final audit report.

FSIS was pleased with the corrective actions indicated during the exit conference on July 1, 2002, and in your letter of October 25, 2002, to resolve the issues raised during the June/July 2002 audit. In particular, FSIS was pleased by the corrective actions taken by the establishments and by the Netherlands in the five establishments that were given a 30-day notice as a result of the audit findings. The corrective actions taken in the four establishments that were not given a 30-day notice or delisted also appear to be satisfactory. As a reminder, each of the three establishments that were delisted will remain delisted until the necessary corrective actions are documented and FSIS auditors or European Commission auditors re-visit the facility to verify that it is complying with all applicable EU and U.S. requirements.

Aside from the audit issues, however, FSIS was concerned with some of your comments in the October 25, 2002 letter. FSIS regrets having to stress our concerns regarding the Netherlands' meat inspection system in our letter dated August 27, 2002. We are confident, however, that the National Inspection Service for Livestock and Meat (RVV) will take these issues seriously and that the results of our upcoming audit will be considerably improved over previous audits. In addition, FSIS is continuing its efforts to make the audits and audit reports less negative, more uniform, and less duplicative.

Of particular concern to FSIS were comments in the above letter indicating that the RVV did not have enough time to implement some of the actions needed to resolve previous audit issues. FSIS expects the corrective and preventive actions necessary to resolve observed audit findings to begin at the time RVV officials are notified of each deficiency. This notification would usually take place prior to the final exit meeting of the audit, well in advance of the date on the final audit report. At the very latest, all audit findings would be relayed to RVV and other Netherlands' officials at the exit conference at the conclusion of the audit.

FSIS is grateful that you have made the noted adjustments to th : Dutch meat inspection system in response to the June/July audit and taken the indicated corre tive and preventive actions. If you have any questions regarding the audit or need additional i formation, please contact me by telephone at (202) 720-3781, by fax at (202) 690-4040, or b e-mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen, Acting Director
Equivalence Staff
Office of International Affairs

Enclosure

FINAL REPORT
OF AN AUDIT CARRIED OUT IN THE NETHERLANDS COVERING THE NETHERLANDS' MEAT INSPECTION SYSTEM

JUNE 5, 2002 THROUGH JULY 1, 2002

Food Safety and Inspection Service
United States Department of Agriculture
July 5, 2002

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Ministry of Agriculture, Nature Management and Fisheries; National Inspection Service for Livestock and Meat)
RVV	National Inspection Service for Livestock and Meat
AID	De Algemene Inspectiedienst or the Inspectorate for Consumer Goods, Ministry of Public Health
FSIS	Food Safety and Inspection Service
VEA	Agreement Between the United States of America and the European Community on Sanitary Measures to Protect Public and Animal Health in Trade in Live Animals and Animal Products (commonly known as the European Community/United States Veterinary Equivalence Agreement)
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*

1. INTRODUCTION

The audit took place in the Netherlands from June 5, 2002 to July 1, 2002. The audit team was comprised of three auditors; two veterinarians from FSIS' Technical Service Center located in Omaha, Nebraska and one Senior Equivalence Officer from the FSIS headquarters in Washington, D.C.

Audit team members were accompanied during the entire audit by representatives from the Central office of the Central Competent Authority (CCA) and/or representatives from the Regional and District inspection offices of the CCA.

An opening meeting was held on June 5, 2002 in The Hague with the CCA. At this meeting, the audit team leader confirmed the objectives and scope of the audit, discussed the itineraries of the audit members, and requested additional information needed to complete the audit of the Netherlands' meat inspection system.

2. OBJECTIVES OF THE AUDIT

This audit had two objectives. The first objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States. The second objective of the audit was to determine if the CCA had taken the necessary corrective actions in response to previous audit findings. If any of the six establishments that were determined marginally-acceptable were not found to be fully acceptable during this visit, the establishment in question would be removed from the list of establishments eligible to export to the United States and will not be allowed to be re-certified by the CCA until FSIS has verified the validity of the re-certification.

In pursuit of these objectives, twelve of nineteen certified establishments were audited on-site, documents relating government records of six establishments were reviewed at the Central office and three laboratories performing analytical testing product destined for the United states were audited. In addition, an investigative department of the Ministry of Public Health, various departments at the headquarters of the CCA, three of five Regional offices, six of seventeen District offices, and eight of forty-eight Team Leaders were also visited. The Regional offices that were not visited during this audit did not supervise establishments that were certified to export to the United States. All of the Regional offices and all, but two, of the District offices that supervise establishments that are certified to export meat products to the United States were visited during this audit. Team Leaders normally supervise one or two U.S. certified establishments. Approximately half of these supervisors were visited and interviewed during this audit.

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to government offices that are involved in the production and export of meat products to the United States to discuss oversight policies and practices. The second part involved on-site visits with CCA officials to U.S. certified establishments. The third part

involved visits to government laboratories that analyze samples for the presence of generic *Escherichia coli* (*E. coli*), *Salmonella* spp, and residues.

The effectiveness of the Netherlands' inspection system was determined by focusing on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and the generic *E. coli* testing program, (4) enforcement controls, including the *Salmonella* spp testing program and (5) residue controls. The Netherlands' inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditors also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the audit team leader explained to the CCA that their inspection system would be audited against the requirements mandated or stipulated in three sets of official documents. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), FSIS auditors would audit the meat inspection system against European Commission Directive 64/433/EEC from June 1964 and EC Directives 96/22 and 96.23 from April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, FSIS auditors would audit against FSIS requirements. These requirements include daily inspection of processing establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, generic *E. coli* testing and *Salmonella* species testing.

Third, FSIS auditors would audit against any equivalence determinations that have been made by FSIS for the Netherlands under provisions of the Sanitary/Phytosanitary Agreement. Currently, the Netherlands has equivalence determinations from FSIS regarding their "generic *E. coli"* testing program and their *Salmonella* spp testing program. These differences can be reviewed respectively under sections 11.2 and 12.1 of this report.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).

- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat

- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products

- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at www.fsis.usda.gov/ofo/tsc.

During the last two FSIS audits of the Netherlands' meat inspection system (February 2000 and October 2001), a number of problems were identified; some of which were repeat deficiencies. In particular, it should be noted that during the October 2001 audit, 6 of the 8 establishments that were audited were determined marginal and two were removed from the list of U.S. certified establishments. None of the establishments were fully acceptable. The following recommendations were derived from the last two audits and are of special relevance for the current audit:

- To strengthen veterinary supervision at all levels to assure compliance with United States requirements.
- To increase the number and/or scope of establishment inspections carried out by the CCA, regional offices, and district offices to ensure a uniform and thorough application of U.S. requirements in relation to the certification of establishments for export and the maintenance of U. S. standards in these establishments.
- To improve daily inspection coverage in all U.S. certified establishments.
- To institute adequate daily inspection coverage in applicable second, and third shift operations.
- To institute adequate daily inspection coverage in processed product establishments and warehouse/freezer facilities.
- To improve the sanitation of facilities and equipment.
- To improve inspection system controls; especially in regard to the adequate identification of edible and inedible product containers and the enforcement of the zero-tolerance for visible fecal material/ingesta contamination and milk on carcasses.
- To institute adequate monthly supervisory visits in all U.S. certified establishments by non-resident supervisory personnel.
- To eliminate the occurrence of actual product contamination.
- To ensure the full implementation of basic SSOP and HACCP requirements.
- To initiate random sample selection when selecting samples for the "generic *E. coli*" (i.e. *Enterobacteriaceae*) and *Salmonella* spp testing programs under PR/HACCP.
- To institute pre-shipment verification reviews on shipped product.
- To improve the quality assurance programs in official laboratories.

- To institute a microbiological monitoring program for finished products, which includes 'scheduled' or 'directed' testing (*Salmonella* and *Listeria)* for ready-to-eat product.

6. MAIN FINDINGS

6.1 Legislation

The audit team was informed that the following relevant EC Directives, determined equivalent under the VEA, have been transposed into Dutch legislation:

- Council Directive 64/433 of June 1964 on health problems affecting intra-community trade in fresh meat
- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products
- Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists

6.2 Competent Authority Control Systems

FSIS regulations require that foreign countries that wish to become eligible to export meat to the United States or to maintain their current eligibility be organized and administered by the national government. More specifically, there must be sufficient organizational structure and staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official activities of all employees and licensees. Third, the national government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection. Finally, the country must have adequate administrative and technical support to operate its inspection program.

The FSIS auditors noted the following:

The organization of the Netherlands' National Inspection Service for Livestock and Meat (RVV) consists of three levels: central, regional, and district. At the central level, RVV is a component of the Ministry of Agriculture, Nature Management and Fisheries. This is the level of government that FSIS holds responsible for ensuring that FSIS regulatory requirements are implemented and enforced. The RVV, with regard to meat inspection, is staffed with approximately 3000 personnel. These personnel are scattered throughout the 12 Provinces of the Netherlands. The boundaries of the five Regional offices correspond to the boundaries established by the Provinces. The Regions are not, however, subject to Provincial rules. The five Regional offices manage seventeen Districts in the Netherlands and the District offices manage 48 Teams. Each Team inspects two or more establishments and is supervised by a Team Leader. Each Team Leader supervises two or more Veterinarians-in-Charge, other full time RVV

Veterinarians, part-time private practitioners, full-time RVV Meat Inspectors, and non-permanent Assistant Meat Inspectors. Overall, approximately 26 veterinarians and 150 inspectors are tasked with providing direct meat inspection services to establishments that are certified to produce or store products for U.S. consumption. There are generally two levels of employment for inspectors and veterinarians at the District level. These two levels consist of full-time, permanent veterinarians or inspectors and part-time and/or non-permanent practitioners (veterinarians) or assistant meat inspectors.

The FSIS audit team was informed of completed, ongoing, and planned changes within the CCA with regard to control of inspection activities in Dutch meat establishments. Although no significant organizational changes have occurred as a result of the findings of the February 2000 and October 2001 audits, the RVV has been in the process of fine tuning the effectiveness of their inspection system. Relatively recent changes involve the use of approximately 11 Central office and Regional auditors. Some auditors perform quality audits on how and if veterinarians and inspectors are doing their job as per RVV developed instructions and checklists and/or compare instructions with the tasks indicated on the checklists to ensure comprehensiveness. These instructions are developed at the Central office. In one of the three Regions visited, the regional auditors certify U.S. certified establishments and/or performed quality audits. Most Regions used the Team Leaders to certify U.S. establishments. In addition, some newly trained auditors throughout the CCA perform process systems audits, primarily auditing establishment's HACCP systems.

Other changes that are planned for the near future involve the addition of specialized personnel to the field Teams. These changes are designed to enhance the ability of the CCA to increase its supervision and control of inspection personnel and activities at the establishment level. Regional and District offices also expect to gain from these changes by reducing some of the staffing and administrative burdens experienced by Team Leaders.

The specialized personnel will replace the chief meat inspectors that now work under the Team Leaders, with two or more of the three specialized positions per team. These positions are senior inspector or foreman, technical-administrative inspector, and auditor for inspection control and auditing. These Team-based auditors will have the responsibility of performing audits of the process systems of establishments, particularly the SSOP and HACCP systems.

In addition, the Regional and District offices are further staffed with Specialists, staffing Planners, administrative personnel, and auditors to assist in implementing an effective inspection system. Regional offices have a Director and a Deputy Director, one of which is a Veterinarian. The other individual is an accountant or an economist or an administrator, etc. by training and experience. This process broadens the information pool available throughout the RVV.

In response to the previous FSIS audits and other events occurring within Europe, the Netherlands reduced the number of U.S. certified establishments from twenty-four to nineteen. In addition, a proposed reorganization will combine the RVV with the Inspectorate for Consumer Goods to create the National Consumer Goods Authority

under the Ministry of Public Health. The Inspectorate for Consumer Goods (or Food Stuffs) currently visits grocery stores, restaurants, and other retail outlets and has the authority to conduct investigations and levy fines. RVV currently uses the AID to conduct these activities. When combined, some current RVV tasks will remain with the Ministry of Agriculture, Nature Management and Fisheries but will be performed by this new authority under a cooperative agreement between the Ministries.

6.3 Ultimate Control and Supervision

As indicated above, the CCA has the legal authority to supervise the activities of the Regional offices, the Regional offices have the authority to supervise the activities of the District offices, and the District offices have the authority to supervise the activities of the Teams. Through this linear system, regulations and instructions are implemented throughout the country. However, the degree to which one office supervises another office and their activities can vary considerable in the detailing of specific information and in the level of personal contact with the individuals being supervised. To begin with, information is normally distributed via a CCA Intranet. This Intranet contains all of the applicable regulations and instructions; with new and updated instructions being identified as such. All applicable regulations are rendered or incorporated into instructions, as needed, by the CCA.

Regulations from non-EU countries are considered bilateral agreements by the CCA. These regulations, when introduced, are translated into Dutch and used to develop new or revised instructions for field personnel to follow. EU Directives are translated into Dutch and incorporated into Dutch legislation. The Dutch legislation is then used to develop new or revised instructions. Checklists are normally developed from one or more instructions, either in part or in total, to ensure that inspection personnel account for all the provisions of the instructions. FSIS auditors verified through audits of the regional and District offices that instructions and checklists were received by and implemented by these offices. The Central office ensures that regulations are properly developed into instructions and, where applicable, into nationally used checklists. Regulations are rarely compared to checklists that are developed at the lower levels for specific purposes. Regional and District offices, with Team Leader assistance, are primarily responsible for ensuring that instructions and national checklists are used appropriately. Team Leaders and each resident Veterinarian-in-charge (VIC) are primarily responsible for ensuring that veterinarians and inspectors carry out the functions noted on the national and locally developed checklists. However, there is very little direct field supervision by the Central office or by the Regional Directors or District Heads to verify the full implementation of legislation and regulatory instructions. Verification of the implementation of these regulations/instructions and the direct supervision of resident veterinarians and inspectors is left up to the Team Leaders. The VICs and, to varying degrees, the Team Leaders are responsible for making sure all appropriate veterinary and inspection activities take place in the establishment to which they are assigned.

In most cases, the supervision of the Regions by the Central office, the supervision of the Districts by the Regional office, and the supervision of the Teams by the District office is through the use of scheduled meetings with specialty groups, management and supervisory personnel and through regularly scheduled reports on various aspects of the

inspection system. Visits to supervised offices or supervised personnel by a supervising office is loosely organized and may or may not result in any documentation of the visit and the issues discussed. Audits for quality and process-controls assist in providing feedback to managers and supervisors. These auditors, however, do not have the authority to correct noted problems and may not be accompanied by those that supervise the establishment and inspection personnel being audited. Consequently, this system seems to rely on 3rd party information to identify performance issues and relies on the ready knowledge and experience of the Team Leader to properly implement instructions and checklists. There is very little over-the-shoulder supervision above the Team level and the coverage of the visits that do occur is relatively sporadic and unspecified by any CCA instructions or guidelines.

6.4 Assignment of Competent, Qualified Inspectors

Full-time, permanent CCA veterinarians must have a Veterinary diploma resulting from a 5-year degree program to be considered qualified to apply for the inspection service. During the coursework, veterinarians receive training in generic slaughter and processing operations and are, therefore, partially trained when they receive their diplomas. After they are hired, and after they review the appropriate training module(s) and have some on-the-job-training (OJT), they may perform certain veterinary duties under the supervision of experienced veterinarians. Within a few months after being hired, each veterinarian takes two weeks of introductory training and six to eight weeks of internship where they learn about how to conduct inspections as a government veterinarian.

Private Practitioners, called Practitioners, are hired on a part-time basis for a maximum of 16 hours per week. These Practitioners usually belong to a Veterinary Clinic or have a clinic of their own and have the same diploma as the full-time CCA veterinarians. They are required to take the public health and/or animal health training modules before they begin work and are counseled on the difference between a private practitioner and a government veterinarian. In addition, they are advised to avoid any situations where a conflict-of-interest might occur and sign an employment contract that includes a confidentiality clause. Practitioners normally perform export inspections of live animals and ante-mortem inspection in slaughter operations. They may also perform other RVV veterinary duties if they are properly trained. Although there are approximately 350 Practitioners used by the CCA, they are never assigned as a VIC or a Team Leader.

Full-time, permanent CCA meat inspectors must have successfully completed 4 years of vocational college training before they meat the minimum qualifications to become hired as a meat inspector. After they are hired, they must successfully complete 9 months to 1 year of inspector training before they can work as a meat inspector in an establishment.

Full-time or part-time, ‘temporary’ assistant meat inspectors have completed 4 years of lower level vocational training before they meet minimum hiring qualifications. Assistant meat inspectors contract with a temporary hiring service and are hired through the service. After they are hired, they must successfully complete 3 to 4 months of inspector training before they can begin inspection duties.

FSIS' PR/HACCP requirements include four program; SSOP, HACCP, generic *E. coli* testing, and *Salmonella* testing. Specific and adequate training in all four PR/HACCP programs was not evident for management and supervisory personnel and for veterinarians and inspectors. For example, even auditors who audit process systems (i.e. HACCP) are provided audit training that only includes some HACCP. The entire auditing course lasts for one week. Most training that is specifically for HACCP lasts for only one day. In addition, training in the SSOP requirements is part of the Netherlands' training in good manufacturing practices (GMP) and does not address the critical differences between GMP and SSOP regarding documentation and the identification of specific points of sanitation.

6.5 Authority and Responsibility to Enforce the Laws

RVV had the authority and responsibility to enforce the applicable laws relevant to U.S. certified establishments. RVV not only has the authority to approve establishments for export to the United States, but also has the responsibility for withdrawing such approval when establishments do not have adequate and/or effective controls in place to prevent, detect, and eliminate product contamination/adulteration. Establishments wishing to export product to the United States must write a letter to the Regional office serving the Province where the establishment is located. The Regional Director or Deputy Director then assigns either a Regional auditor or the appropriate District office the task of auditing the establishment and making a recommendation report to the Regional office. If approved, the recommendation is forwarded to the Central office for confirmation and U.S. notification. The establishment must have already complied with domestic and EC approval requirements and has less than six weeks to show compliance with U.S. requirements. The Veterinarian-in-Charge and the Team Leader are ultimately responsible for working with the establishment and ensuring compliance.

The CCA is currently staffed by over 3000 employees. The Central office has approximately 220 employee with 24 in the veterinary services, 8 in the instructions services, 10 in quality management, 10 in animal disease control, and 30 in inspection services. The rest are support personnel. Within these departments, there are approximately 48 veterinarians. In the field, veterinarians and inspectors ensure compliance with all applicable regulations and instructions in the 19 U.S. certified establishments. In certified establishments, there are approximately 26 veterinarians and 150 meat inspectors. Within the Regions and Teams of the RVV, there are approximately 11 auditors. This number will increase with the elimination of the chief meat inspector position (each Team having one or more of these employees). In September of this year, three new positions will be created. As stated earlier, each Team will have one person for Inspection Control and Auditing and one for Technical Administration. Teams that have one or more larger establishments will also have a Senior Meat Inspector or Foreman. Each of these special Team members also works in an establishment.

In addition, each of the five Regions is lead by a Director and a Deputy Director, one of which is a veterinarian. Each Region also has four Specialists; one each in red meat, poultry, livestock, and live animal products, and one quality officer. Specialists are used to provide technical advice on regulations and instructions to field personnel. Each

Region has two or more Districts that they supervise. Each of the 17 Districts has one District Head and two or more Team Leaders. The 48 Team Leaders are the first line supervisors for a group of establishments and are supported by the staff noted above and by the Veterinarian-in-Charge or Inspector-in-Charge of each establishment. These offices and personnel were ultimately responsible for enforcing EC, FSIS, and Dutch legislation within the CCA and were directly responsible for regulatory compliance in U.S. certified establishments.

6.6 Adequate Administrative and Technical Support

During this audit, the auditors found that the CCA had begun applying resources to support more thorough and appropriate third party audits and in-house inspection reports. In addition, the CCA will soon begin to position more specialized personnel at the Team level to enhance the exposure and experience applied to the auditing and supervisory processes. At the Ministry level, the Netherlands has already made some changes toward an overarching authority that will absorb or oversee the food safety aspects of the Ministry of Public Health and the Ministry of Agriculture, Nature Management and Fisheries.

At the Regional level, the CCA currently uses Specialists to review technical instructions and Central office checklists. Regional Directors and District Heads meet with Specialists when their advice is needed. Team Leaders meet with and consult Regional Specialists to ensure that field veterinarians and inspectors are adequately informed.

7. ESTABLISHMENT DELISTMENTS/NOTICES

FSIS auditors visited 12 establishments in total—6 slaughter establishments and 6 cut-up or processing establishments. Three establishments were delisted as a result of the reviews and five were given a 30-day notice for failing to adequately implement the PR/HACCP programs. These establishments will be required to properly implement the inadequate program(s) within 30 days or U.S. certification will be withdrawn by the CCA. The corrective actions taken by the CCA and the establishment will need to be sent to FSIS for review. If the establishment is delisted and requests re-certification, a complete U.S. certification will be required.

In the three establishments that were delisted, there were noted trends or similarities, many of the deficiencies were repeated deficiencies from the previous audit, and the inspection officials did not always take immediate or adequate corrective actions. In the five establishments that were given a 30-day notice, there were noted trends or similarities, the deficiencies were not repeated from the previous audit (except in one establishment), and the inspection officials took corrective action**.** In the remaining four establishments where deficiencies were found, there were noted trends or similarities, the deficiencies were not repeat, and the inspection officials took some immediate corrective actions.

8. LABORATORY AUDITS

The FSIS auditor visited three laboratories during this audit, the National Institute of

Public Health and Environment (RIVM) in Bilthoven and the State Institute for Quality Control of Agriculture Product Laboratory (RIKILT) and National Inspection Service for Livestock and Meat Laboratory (CLRVV) in Wageningen. RVIM was visited on June 24, 2002. The other laboratories were visited on June 25, 2002.

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. In addition, information was secured regarding the oversight of accredited, approved, and private laboratories and the procedures used for intra-laboratory quality assurance programs, including sample handling and methodology.

The National Institute of Public Health and Environment (RIVM) in Bilthoven is the Netherlands National Reference Laboratory (NRL) and also houses facilities for the EC Community Reference Laboratory (CRL). RIVM is not directly involved with analyzing of any residue or microbiological samples from any US approved plants.

The State Institute for Quality Control of Agricultural Products Laboratory (RIKILT) in Wageningen had effective controls in place for sample handling and frequency, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, and percent-recovery frequencies. In addition the methods used for sample analyses were acceptable and, as expected, no composting of samples was performed.

All deficiencies noted during last years audit had been corrected except the following: Laboratory had not performed any proficiency test for chloramphenicol. They were waiting for arrival of the chloramphenicol check samples from FAPAS (The Food Analysis Performance Scheme) of the UK Ministry of Agriculture, Fisheries and Food at time of the visit.

National Inspection Service for Livestock and Meat Laboratory (CLRVV) in Wageningen is one of several government laboratories in the Netherlands in which microbiological testing for *Salmonella*. The following deficiency was noted:

- RVV does not have a microbiological program for testing of ready-to-eat products for *Listeria monocytogenes.* Therefore, none of the laboratories were performing analysis for this pathogens in ready-to-eat products

Specific documentation for each Laboratory is noted on the Foreign Country Laboratory Review report attached to this report.

9. SANITATION CONTROLS

As stated earlier, FSIS auditors focused on five areas of risk to assess the Netherlands' meat inspection system. The first of these risk areas that FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, the Netherlands' inspection system had controls in place for import/export requirements, establishment ventilation and water

supply, dressing room and lavatory facilities, employee hygiene, and control of condemned product. Six of the twelve establishments had all miscellaneous sanitation controls in place. Six establishments did not have fully adequate controls in place, as follows:

- Four establishments did not have adequate controls in place to maintain establishment grounds and prevent pests in and around establishment facilities.
- Four establishments did not adequately control the potential contamination of sanitary operations.
- Four establishments had inadequate controls in place to prevent potentially insanitary equipment or utensils.
- One establishment did not adequately maintain establishment construction/facilities.
- One establishment had inadequate lighting at the dropped meat-reconditioning table.
- One establishment did not adequately control pooled water in edible product area.

Specific documentation for each deficiency found in each establishment is noted on the Individual Foreign Establishment Audit Form attached to this report.

9.1 SSOP Implementation

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. In all but one of the 12 establishments, the basic SSOP requirements were met. The one deficiency was as follows:

- One establishment did not have the person with overall on-site authority date and sign the SSOPs.

Only two of the twelve establishments had adequately performed all of the ongoing requirements under SSOP. The following bullets summarize the deficiencies noted by the auditor:

- Two establishments did not adequately implement the procedures to monitor the implementation of SSOPs.
- Five establishments were not routinely monitoring the effectiveness of the SSOPs.
- Nine establishments did not adequately prevent the occurrence of insanitary conditions through the use of SSOPs.
- Six establishments were not adequately documenting pre-operational and operation sanitation deficiencies.
- No deficiencies were noted during review of the government records of at the Central office**.**

Specific documentation for each deficiency found in each establishment is noted on the Individual Foreign Establishment Audit Form attached to this report. In addition, government and establishment personnel did not seem to have sufficient training or knowledge of SSOP programs as required by FSIS.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, ante-mortem inspections and dispositions, and procedures for sanitary handling of returned and reconditioned product.

There were reported cases of foot-and-mouth disease (FMD) in the Netherlands since the previous audit. In addition, the Netherlands is not declared free from hog cholera disease by APHIS, although OIE has declared Netherlands free of the disease. The Netherlands exports only processed pork products to the United States. Product must be cooked (to at least 69° C), cured and dried (at least 90 days), or canned (shelf stable-sealed, then cooked). Product prepared from beef of Netherlands origin is not eligible for export to U.S. due to bovine spongiform encephalopathy (BSE).

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls required of U.S.-export establishments include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and implementation of an *enterobacteriaceae* testing program in slaughter establishments.

11.1 HACCP Implementation.

All establishments approved to export meat products to the U.S. are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the 12 establishments. All but four establishments adequately implemented the basic HACCP requirements. The applicable deficiencies in these establishments were as follows:

- One establishment did not conduct a hazard analysis for packaging materials.
- Three establishments did not address all three food safety hazards that are likely to occur.
- Two establishments that produced ready-to-eat products did not address the control of *Listeria monocytogenes* in their hazard analysis. *This was a repeat deficiency.*

Only one of the twelve establishments had adequately performed all of the ongoing requirements under HACCP. The following bullets summarize the deficiencies noted by the auditor:

- Nine establishments did not adequately perform verification procedures.
- Five establishments did not validate their HACCP plans.
- Ten establishments did not adequately address the corrective or preventative actions required in response to a deviation.
- Six establishments did not adequately monitor the established critical control points.
- Three establishments did not indicate the actual date, time, and/or initials pertaining to actual deviations.

Specific documentation for each deficiency found in each establishment is noted on the Individual Foreign Establishment Audit Form attached to this report. In addition, government and establishment personnel did not seem to have sufficient training or knowledge of HACCP programs as required by FSIS.

11.2 Testing for Generic *E. coli*

The Netherlands has adopted an equivalent *Enterobacteriaceae* testing program to the FSIS regulatory requirements for generic *E. coli* testing. Six of the 12 establishments audited were required to meet the equivalent of the basic FSIS regulatory requirements for generic *E. coli* testing. These six establishments were evaluated according to the criteria employed in the U.S. domestic inspection program or submitted by the CCA and determined equivalent by FSIS, as applicable.

The alternative, equivalent sanitary measures involve using *Enterobacteriaceae* instead of generic *E. coli* as an indicator organism, sampling based on a testing frequency of ten tests per week rather than based on production, sampling swine from the flank, brisket, rump, and back rather than the ham, belly, and jowl, and using the cork-borer method of sample collection rather then the sponge or excision method.

Equivalent generic *E. coli* testing (i.e. *Enterobacteriaceae* testing) was properly conducted in five of the six slaughter establishments. However, the following deficiency was noted in one slaughter establishment:

- One establishment did not designate the responsible person(s) for taking the samples.

12. ENFORCEMENT CONTROLS

The fourth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between

establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic or EU market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

The CCA, however, did not have all enforcement controls in place that are required by FSIS regulations. The following inadequacies were found:

- In nine establishments, the CCA did not fully verify the adequacy of each establishment's HACCP plan(s) by reviewing and observing every regulatory requirement established for FSIS HACCP plans.
- In five establishments, the CCA did not fully verify the adequacy and effectiveness of each establishment's SSOP by reviewing and observing all of the regulatory requirements established for FSIS SSOPs.

Specific documentation for each deficiency found in each establishment is noted on the Individual Foreign Establishment Audit Form attached to this report.

12.1 Testing for *Salmonella* species

Prior to this audit, the Netherlands had advised FSIS that it had stopped using the cork-borer method of sample collection and were now using the sponge method of sample collection when sampling for *Salmonella* species under the PR/HACCP regulations. Alternative sampling procedures associated with the cork-borer method have also been discontinued. Consequently, the depth of the excision, the size of the sampled area, and the compositing of the samples into a whirl-pack no longer apply to the Netherlands' equivalence determination for *Salmonella* testing. All other alternative sanitary measures were previously determined equivalent and are summarized below. The use of the sponge method of sample collection was the same as that used by FSIS.

Six of the 12 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the United States domestic inspection program or according to the alternative sanitary measures determined equivalent by FSIS, as applicable.

The alternative, equivalent sanitary measures involve using a continuous, on-going sampling program to determine when to initiate additional, targeted sampling for *Salmonella* spp rather than a sampling program based on production; sampling at the end of the slaughter or production process and prior to the carcass being cut and/or packaged rather than from chilled carcasses; and using ISO 6579 to analyze for *Salmonella* instead of FSIS' method.

No deficiencies were observed.

12.2 Species Verification Testing

At the time of this audit, the Netherlands was required to test product for species verification. Species verification testing was being conducted in those establishments required to test for species verification.

12.3 Monthly Reviews

During this audit it was found that in eight of the twelve establishments visited, monthly supervisory reviews of certified establishments were being performed and documented. However, the auditor observed the following deficiency:

- In five establishments, supervisory reviews were not conducted on a monthly basis.
- In two establishments, the reviews that were conducted did not reflect the conditions of the establishment.

In addition, the typical monthly reviews were inadequate, covering only three areas of inspection. In many instances, it would take about a year to cover all areas of inspection. FSIS has determined that all areas of inspection should be covered to some degree during each supervisory visit. These reviews were being performed by auditors from the Regional offices or by the Team Leaders. Access to these reviews varied. Non-inspection records, audit files, and U.S. certification documents were kept in the either the Regional or District office, depending on the Region. Team Leader supervisory reports and inspection records of certified establishments were usually kept in the inspection offices of the individual establishments.

12.4 Inspection System Controls

12.4.1 Daily Inspection in Processing Establishments

The auditors found that daily inspection had been implemented in all twelve of the establishments that were visited when product was produced for U.S. export.

12.4.2 Post-Mortem Inspection Procedures

Six slaughter establishments were audited and required to meet applicable FSIS and EC slaughtering requirements. The following deficiencies were observed with respect to post-mortem inspection procedures:

- In one establishment, CCA personnel were not palpating the liver.

12.5 Enforcement of EC Directives

As noted earlier, FSIS audited against applicable FSIS regulations and against the provisions of EC Directives 64/433, 96/23, and 96/22. All of the provisions of EC

Directive 64/433 were not fully and effectively implemented in each establishment, as follows:

- Six establishments did not fully comply with the provisions established in EC Directive 64/433 as noted in the attached audit forms covering each establishment.

Compliance with EC Directives 96/23 and 96/22 was determined adequate.

12.6 Investigations

RVV is not currently authorized to investigate violations of applicable Dutch law. They are not authorized to bring charges against an establishment or individual or to levy fines against them. The General Inspection Service (AID) of the Ministry of Public Health is used for this purpose. AID has offices throughout the Netherlands and can be contacted by any RVV manager, supervisor, veterinarian, or inspector. AID is authorized to investigate potential violations, bring charges against individuals or firms, make arrests, seize product or property, and levy fines for violations against specific Dutch legislation. Depending on the case, the District office may initiate or be asked to develop a file to assist AID in their investigation, the court case, arrest, seizure, or the determination and support of a fine. In all cases, the District must file a case report when advising AID of a potential violation. One example is when a swine transport vehicle is dirty. The RVV calls AID. AID comes to the establishment and levies a fine against the appropriate transporter. The fine is automatic and pre-determined, by law, in such cases. Other situations may involve more supporting evidence and investigative activities, including a judicial trial.

13. Residue Controls

The Netherlands National Residue Testing Plan for 2002 was being followed, and was on schedule. The Dutch inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

The National Program for Residue Control is based on European Community legislation in force related to the ban of hormonal substances (Council Directive 96/22/EC April 1996) and the control of residues on live animals and animal products (Council Directive 96/23/EC of April 1996). CCA compliance with these Directives was satisfactory.

RVV has specific responsibilities when positive samples are encountered. Depending on the substance in question, the Regional offices are responsible for ensuring that each case of reported positive results are tracked and resolved on a case-by-case basis. When animal samples are found to be positive, the General Inspection Service (AID) from the Ministry of Public Health conducts an investigation into the cause of the violation. Animals from which positive samples are taken are seized and destroyed and fines are levied where appropriate.

14. RECOMMENDATIONS

To ensure full compliance with and the continued enforcement of United States requirements in certified establishments and because of new European Commission inspection requirements effective June 2002, FSIS has several recommendations.

The following recommendations were developed for the CCA in regard to inspection and supervisory coverage of the existing 19 establishments certified for export to the U.S.:

- Standardize the personnel in each Region that are responsible for certifying establishments that wish to export meat products to the United States.
- Standardize the frequency and content of supervisory visits by all four levels of supervision; Central, Regional, District, and Team Leader.
- Standardize the personnel and increase the coverage and scope of the monthly supervisory reviews required by FSIS.
- Initiate a standard and documented procedure for verifying the correct implementation of regulations and instructions at the establishment level and above.
- Query and observe all U.S. certified establishments to ensure that the inspection personnel and the establishments are in full compliance with HACCP and SSOP programs as required under FSIS regulations.

With regard to training, FSIS recommends the following:

- Encourage participation of representatives from the Regional and District offices, including the Team Leaders, at the FSIS training offered at College Station, Texas at A&M University.
- Develop modules and initiate the use of a specific and focused training course on the implementation of FSIS' SSOP and HACCP programs.
- Require adequate training in the PR/HACCP programs of responsible establishment personnel, as required by FSIS.
- Use video conferences with laboratories to share scientific information.
- Schedule additional supervisory training for Regional and District managers, supervisors, and specialists that will ensure the enforcement of United States requirements

General Recommendations:

- The CCA should strengthen its oversight of all levels of authority that are responsible for U.S. certified establishments.
- The CCA should strengthen its oversight of laboratories that analyze samples from certified establishments.

15. CLOSING MEETING

A closing meeting was held on July 1, 2002 with the CCA, Ministry of Agriculture, Nature Management and Fisheries; National Inspection Service for Livestock and Meat At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

16. ATTACHMENTS TO THE AUDIT REPORT

Note the attached Individual Foreign Establishment Audit Forms.

Dr. Faiz Choudry
International Auditor

_____

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
6/25/02	Laboratory of the Inspection Service for Livestock and Mea (RVV)

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Inspection Service for Livestock and Meat	Wageningen, Netherlands	Postbus 44 6700 AC Wageningen

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faiz R. Choudry	Dr. Ron Dwinger; Mr. H.J. Keukens, Head of Laboratory for Livestock and Meat

	Residue Code/Name ▶			200	203	500	800	923	Sul	Entb					
	REVIEW ITEMS	ITEM #													
SAMPLING PROCEDURES	Sample Handling	01	EVALUATION CODE	A	A	A	A	A	A	A					
	Sampling Frequency	02		A	A	A	A	A	A	A					
	Timely Analyses	03		A	A	A	A	A	A	A					
	Compositing Procedure	04		O	O	O	O	O	O	O					
	Interpret Comp Data	05		O	O	O	O	O	O	O					
	Data Reporting	06		A	A	A	A	A	A	A					
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A					
	Correct Tissue(s)	08		A	A	A	A	A	A	A					
	Equipment Operation	09		A	A	A	A	A	A	A					
	Instrument Printouts	10		A	A	A	A	A	O	O					
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O	O	A	A	A	O	O					
	Recovery Frequency	12		O	O	A	A	A	O	O					
	Percent Recovery	13		O	O	A	A	A	O	A					
	Check Sample Frequency	14		A	A	A	A	A	A	A					
	All analyst w/Check Samples	15		A	A	A	A	A	A	A					
	Corrective Actions	16		A	A	A	A	A	A	A					
	International Check Samples	17		O	O	O	O	O	O	O					
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O					
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

M Choudry

DATE

6/26/02

FSIS FORM 9540-1 (9/96)

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE	NAME OF FOREIGN LABORATORY
	6/25/02	Laboratory of the Inspection Service for Livestock and Meat (RVV)

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
National Inspection Service for Livestock and Meat	Wageningen, Netherlands	Postbus 44 6700 AC Wageningen

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faiz R. Choudry	Dr. Ron Dwinger; Mr. H.J. Keukens, Head of Laboratory for Livestock and Meat

RESIDUE CODES	ITEM NO.	COMMENTS

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
6/25/02	State Institute for Quality Control of Agricultural Products (RIKILT)

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Department of Wageningen University and Research Center (WUR)	Wageningen, Netherlands	Building No. 123 Bornsesteeg 45, Wageningen

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faiz R. Choudry	Dr. R. Dwinger; P.H.U. de Vries, Head Dept of Assurance; and Mr. A. Roos, QA

	REVIEW ITEMS	ITEM #	EVALUATION CODE	100	111	300	400	500	600
	Residue Code/Name ▶			100	111	300	400	500	600
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A
	Sampling Frequency	02		A	A	A	A	A	A
	Timely Analyses	03		A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O
	Data Reporting	06		A	A	A	A	A	A
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A
	Correct Tissue(s)	08		A	A	A	A	A	A
	Equipment Operation	09		A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	A	A
	Recovery Frequency	12		A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	A	A
	Check Sample Frequency	14		A	A	A	A	A	A
	All analyst w/Check Samples	15		A	A	A	A	A	A
	Corrective Actions	16		A	A	A	N	A	A
	International Check Samples	17		A	A	A	A	A	A
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O
OTHER REVIEW		19	EVAL. CODE						
		20	EVAL. CODE						

SIGNATURE OF REVIEWER: M. Thias mughal

DATE: 6/25/02

FSIS FORM 9500-1 (5/00)

Designed on FormFlow Software

FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)*	REVIEW DATE 6/25/02	NAME O FOREIGN LABORATORY State Ins itute for Quality Control of Agricultural Product (RIKILT)
FOREIGN GOV'T AGENCY Department of Wageningen University and Research Center (WUR)	CITY & COUNTRY Wageningen, Netherlands	ADDRES S OF LABORATORY Buildin No. 123 Bornsesteeg 45, Wageningen
NAME OF REVIEWER Dr. Faiz R. Choudry	NAME OF FOREIGN OFFICIAL Dr. R. Dwinger; P.H.U. de Vries, Head D pt of Assurance; and Mr. A. Roos, QA	

RESIDUE CODES	ITEM NO.	COMMENTS

Attachment F

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Van den Bergh Nederland Sourcing Unit Unox Oss	06/18/02	55	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7 Written SSOP	
8 Records documenting implementation.	
9 Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11 Maintenance and evaluation of the effectiveness of SSOP's.	
12 Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13 Daily records document item 10, 11 and 12 above	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14 Developed and implemented a written HACCP plan.	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16 Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27 Written Procedures	0
28 Sample Collection/Analysis	0
29 Records	0
Salmonella Performance Standards - Basic Requirements	
30 Corrective Actions	0
31 Reassessment	0
32 Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag	
43. Water Supply	
44. Dressing Rooms/Lav tories	
45. Equipment and Utens ls	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov rage	
51. Enforcement	X
52. Humane Handling	0
53. Animal Identificatior	0
54. Ante Mortem Inspec ion	0
55. Post Mortem Inspec ion	0
Part G - Other Regulatory Oversight Requirements	
56 European Commun y Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands Est. 55 Date of Audit: June 18, 02

20. Corrective actions did not meet all the requirements of FSIS Reg. 417.3: No preven ive action actions were recorded when deviations were found.

38 and 56.One fly was observed in the meat processing area. Plant officials took imr iediate action to kill it. This does not comply with the EC Council Directive 64/433 Chapter II 2 (m)

51. Government Inspectors had identified problems in SSOP and HACCP but were no following up on any corrective action taken (or not taken) by plant officials. Inspectors visit the plant 8 to 12 times per year. Iowever, plant has not exported directly or indirectly to the US since 1996. There were no US approved labels on hand

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Ghias Mughal	Dr. Ghias Mughal 6/18/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklis :

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Weert B. V. Weert	06/13/02	64	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faiz R. Choudry		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requireme its. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	X
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Pa D - Continued Eco omic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds nd Pest Control	
39. Establishment Construc ion/Maintenance	X
40. Light	X
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavat ries	
45. Equipment and Utensil	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product C ntrol	
Part F - I spection Requirements	
49. Government Staffing	
50. Daily Inspection Cover ge	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspectic n	
55. Post Mortem Inspectic n	X
Part G - Other Re ulatory Oversight Requirements	
56. European Community I irectives	X
57. Monthly Review	X
58. Intended Enfo cement Actions	X
59.	

60. Observation of the Establishment

11. Establishment officials were not routinely evaluating the effectiveness of the Sanitation SOP's to prevent direct product contamination or adulteration of product.

12. An employee was observed keeping his foot on automatic viscera conveyor pan during evisceration operation in the slaughter room. Establishment official took corrective action immediately.

13. The daily pre-operational and operational sanitation deficiencies were not identified and any corrective action taken were not documented by the establishment officials.

19. Ongoing verification of direct observations of monitoring activities, corrective actions, direct measurement of the CCP's did not meet FSIS 417.2(c)(7), 417.4(a)(2). The HACCP plan was not validated. *Repeat deficiency from last audit.*

20. Corrective action written in HACCP for monitoring and ongoing plant verification did not meet FSIS 417.3(a) regulatory requirements. *Repeat deficiency from last audit.*

22. The records were not maintained for monitoring CCP's for zero tolerance for fecal naterials and corrective and preventive actions taken in response to a deviation of CL's did not meet FSIS 417.5 regulatory requirements adequately. *Repeat deficiency from last audit.*

27. The procedure did not designate the employees' responsible to collect the sample testing for Enterobacteriaceae

39/56. a) Overhead pipes and beams in the boning room were observed with accumulation of dust, dirt, grease, dried pieces of fat and meat. Council Directive 64/433/EEC. Chapter III.4 was not met.
b) Overhead electrical wires at the inspection slaughter line were observed with accumulation of dust, dirt, and wet. Council Directive 64/433/EEC. Chapter III. 4 was not met.

40/56. Light was not 540 lux at the dropped meat reconditioning table in the boning room. Establishment officials ordered correction. Council Directive 64/433/EEC. Chapter II.2(h) was not met.

45/56. a) The sanitizing facility for knives in the processing room were designed in such a way that it was not possible to sanitize knife completely and effectively. Establishment officials ordered correction. Council Directive 64/433/EEC. Annex I, Chapter I.(q) was not met.
b) Automatic hog heads conveyor belt had broken and deteriorated paddles in the shipping area. Establishment officials ordered correction. Council Directive 64/433/EEC. Chapter III.3(c) was not met.

46/56. a) Beaded condensation was observed in the cooler and cut-up room. Council Directive 64/433/EEC. Chapter III. 3(c) was not met.
51. a) Veterinary meat inspector did not meet 417.8 regulatory requirements such as reviewing the CCP records, reviewing and determining the adequacy of corrective actions taken when a deviation occurred, direct observation or measurement at a CCP, on-site observation and record review.
b) Meat inspection officials most of the time were not identifying the pre-operational and operational sanitation deficiencies and any corrective actions taken were not documented.
55/56. The liver and mesenteric lymph nodes were not palpated by the inspector. Council Directive 64/433/EEC. Chapter VI 25(g) was not met.
57. Monthly supervisory three audits were conducted since December, 2001. These audits did not reflect the conditions of the establishment.
58. GON inspection officials indicated that establishment would be given 30 days notification of intended enforcement actions related to HACCP system inadequacy determinations on June 13, 2002.

Establishment # 64 Audit date 06/13/02

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	Faiz R. Choudry 6/13/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1 ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Scherpenzeel B. V. Scherpenzeel	06/20/02	82	Netherlands
	5. NAME OF AUDITOR(S)		6 TYPE OF AUDIT
	Dr. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag	
43. Water Supply	
44. Dressing Rooms/Lav tories	
45. Equipment and Uten ils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Co erage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identificatio	O
54. Ante Mortem Inspec ion	O
55. Post Mortem Inspec ion	O
Part G - Other Regulatory Oversight Requirements	
56. European Commun y Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Netherlands Est. 82 Date of Audit: June 20, 02

10 Sanitation deficiencies are not clearly identified and no preventive action are taken when problems observed. Documents stated only as " corrected"

11. Dried blood, fat and meat residues observed on some hooks in the meat receiving area and on some meat tubs ready for use. Plant officials took immediate corrective action.

15. Hazard analysis was incomplete. It did not address all the three food safety hazards One CCP (e.g. CCP1) was being monitored at two different locations. Monitoring and verification of CCPs has not been clearly stated
Plant officials did not seem to have proper HACCP training. HACCP Team had not been clearly identified in the HACCP Plan.
20. Corrective actions did not meet all the requirements of FSIS Regulation 417.3. The plant officials did not address preventive actions.
51. GON Inspectors were not clearly identifying deficiencies found during their checks. Records stated equipment was "dirty". A new checklist is being developed by in-plant Inspectors.

Government Officials were informed to issue a "thirty day Letter" and send response to FSIS Officials in DC.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Ghias Mughal	M Ghias Mughal 6/20/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco S- Hertogenbosch B. V. S-Hertogenbosch	06/10/02	89	Netherlands
	5. NAME OF AUDITOR(S) Dr. Faiz R. Choudry		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	X
58. Intended Enforcement Actions	X
59.	

60. Observation of the Establishment

12. Several employee's were not using hygienic work habits to prevent direct product c ontamination such as: Employee's were observed handling unclean equipment, picking up pieces of meat from the floor ar d, without washing hands handled edible product; An other employee picked up gloves from the floor and, without washir g hands and washing/sanitizing gloves handled edible product in the boning. Establishment officials took corrective ac ions immediately.

13. The daily pre-operational and operational sanitation deficiencies some time were n ot identified and any corrective action taken were not documented by the establishment officials. Establishment officials ord ed correction.

18. Monitoring procedures identified in the HACCP plan were not adequately perform d such as CCP's were not identified in the monitoring records; Chemical and microbiological CCP's were monitored as a o e CCP. FSIS 417.2(c)(4) regulatory requirements was not adequately met.

19. Ongoing verification activities such as direct observations of monitoring activities corrective actions, direct measurement at a CCP and reviews of records were not met adequately FSIS 417.2(c) ', 417.4(a)(2), and 417.5(c) regulatory requirements.

20. The HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits for ammonia and freon CCP in the cooler. Plant records, however, did not indic ite any such deviation had occured. FSIS 417.3(a)2 and 417.5(a)(3) regulatory requirements was not adequately met.

22. Monitoring, corrective actions, and plant verification records were not adequately naintained. The HACCP plan called for monitoring of CCP for product temperature at five different locations at the produc receiving room. Some time only three temperature readings were recorded. No plant verification records were maintai ed. FSIS 417.5 regulatory requirements was not adequately met.

51. Veterinary meat inspector did not meet 417.8 regulatory requirements such as rev ewing the CCP records, reviewing and determining the adequacy of corrective actions taken when a deviation occurred, direc observation or measurement at a CCP, on-site observation and record review.

57. Monthly supervisory one audit was conducted since January 01, 2002

58. GON inspection officials indicated that establishment would be given 30 days no ification of intended enforcement actions related to HACCP system and SSOP inadequacy determinations on June 10, 2)02.

Establishment # 89 **Audit date 06/10/02**

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND)ATE
Dr. Faiz R. Choudry	6/10/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zwanenberg Food Group B.V. Almelo	06/11/02	129	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faiz R. Choudry		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	X
58.	
59.	

60. Observation of the Establishment

19. Direct observation or direct measurement at a CCP were not performed during plan ongoing verification. Establishment officials ordered correction immediately. FSIS 417.4(a)(2)(ii) regulatory requirements were not adequately met.

22. The records document monitoring of the CCP's and critical limits (CL's) but actual time and signature/initials was not recorded. FSIS 417.5 regulatory requirements was not adequately met. Establishment officials ordered correction immediately.

51. Veterinary meat inspector did not adequately meet FSIS 417.8 regulatory requirements.

57. Monthly supervisory two audits were conducted since January 01, 2002.

Establishment # 129 Dated 06/11/02

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faiz R. Choudry	Faiz R Choudry 6/11/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zwanenberg Food Group B. V. Raalte	06/19/02	153	Netherlands
	5. NAME OF AUDITOR(S) Dr. Ghias Mughal		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7 Written SSOP		33. Scheduled Sample	
8 Records documenting implementation.		34. Species Testing	
9 Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X	38. Establishment Ground and Pest Control	
13. Daily records document item 10, 11 and 12 above		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	X
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53 Animal Identification	O
26 Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54 Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55 Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56 European Community Directives	
29 Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58	
30. Corrective Actions	O	59	
31. Reassessment	O		
32 Written Assurance	O		

60. Observation of the Establishment

Netherlands Est. 153 .. Date of Audit: June 19, 02

11. Dried meat and fat was observed on two lids, one ladle, one meat buggy, and rust was noted on two meat screens, all were ready for use. Establishment officials ordered immediate corrective action.

12. No corrective actions were documented for any sanitation deficiencies identified by the plants.

50. Inspector visits plant 1-2 times per week. Team leader visits once per week. Plant is supposed to notify GON Officials three weeks in advance of the day US product would be processed in order for inspector to be present on the days of processing of US product.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Ghias Mughal	M. Ghias Mughal 6/19/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checkli st

1 ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hendrix Meat Group B.V. Emmen	06/21/02	160	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Ghias Mughal		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirem :nts. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7 Written SSOP	
8 Records documenting implementation	
9 Signed and dated SSOP, by on-site or overall authority	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13 Daily records document item 10, 11 and 12 above	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14 Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16 Records documenting implementation and monitoring of the HACCP plan	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27 Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30 Corrective Actions	
31 Reassessment	
32. Written Assurance	

P rt D - Continued Ec onomic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36 Export	
37. Import	
38. Establishment Ground and Pest Control	
39. Establishment Constr ction/Maintenance	
40. Light	
41 Ventilation	
42. Plumbing and Sewag	
43 Water Supply	
44 Dressing Rooms/Lav tories	
45. Equipment and Uten ls	
46. Sanitary Operations	
47 Employee Hygiene	
48 Condemned Product Control	
Part F Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov rage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspec on	
55 Post Mortem Inspec on	
Part G - Other R gulatory Oversight Requirements	
56 European Communit Directives	
57 Monthly Review	
58	
59	

60. Observation of the Establishment

Netherlands Est. 160 . Date of Audit: June 21, 02

12. No corrective action had been documented on several deficiencies noted by the pl nt officials and preventive action concept was not understood and applied.

15. Hazard analysis did not account for all the three hazards identified in the plant haza d analysis.

19. Establishment employees perform 100 per cent monitoring of carcasses for presenc e of carcasses. Contaminated carcasses were being marked for trimming but no monitoring records were maintained Verification procedure for zero fecal tolerance had a 5 per cent action limit. No corrective action was being taken unless fec s were found on two carcasses.

20. Corrective actions for the food safety deficiencies noted did not meet all the requi ements of FSIS Regulation 417.3. No preventive actions had been recorded.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Ghias Mughal	M. Ghias Mughal 6/21/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklis

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	. NAME OF COUNTRY
Hendrix Meat Group C. V. Meppel	06/12/02	193	Netherlands
	5. NAME OF AUDITOR(S)		. TYPE OF AUDIT
	Dr. Faiz R. Choudry		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requiremer ts. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Par D - Continued Eco omic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - ther Requirements	
36. Export	
37. Import	
38. Establishment Grounds nd Pest Control	X
39. Establishment Construc on/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavat ies	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product C ntrol	
Part F - I spection Requirements	
49. Government Staffing	
50. Daily Inspection Cover ge	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspectio	
55. Post Mortem Inspectio	
Part G - Other Reg ulatory Oversight Requirements	
56. European Community I irectives	X
57. Monthly Review	X
58. Unacceptable	X
59.	

60. Observation of the Establishment

10. Implementation of the procedures in the SSOP's did not meet FSIS 416.13(c) regula ory requirements.
11. Establishment officials were not routinely evaluating the effectiveness of the Sanitati on SOP's to prevent direct product contamination or adulteration.
12. a) Several sanitizers were not maintained at the required temperature (82C) in the sl ughter and boning rooms. Establishment officials ordered correction immediately. *Repeat deficiency from last aud .*
b) Fat residue and grease was observed on automatic conveyor belt for edible product r ady for use but not in use in the boning room. Establishment officials ordered correction. *Repeat deficiency from last au it.*
c) Several plastic containers, combo bins, and offal trees for edible products in the bon ng room, offal room, and coolers were found with grease, fat residue, blood, and extraneous materials from previous day's operation on product contact surfaces. Establishment officials corrective actions were inadequate. *Repeat deficiency rom last audit.*
d) Hog carcasses were contacting employee's boots and work platform at the carcass tr mming station. Neither establishment nor GON meat inspection officials took corrective actions. *Repeat defici ncy from last audit.*
e) Dripping condensate, from overhead pipe that was not cleaned/sanitized daily, was f lling onto edible product in the shipping room. Neither establishment nor GON meat inspection officials took corrective actions.
13. The daily pre-operational and operational sanitation deficiencies most of the time w re not identified and any corrective action taken were not documented by the establishment officials. *Repeat deficiency fron last audit.*
14. The establishment did not conduct a hazard analysis in its HACCP plan for packagi g materials.
18. The HACCP plan monitoring procedures were not adequately performed such as fo zero tolerance for fecal contamination, up to 5% the cause of the deviation was identified and not eliminated. E en between 7% to 13% deviation of CCP's, no measures were established to prevent recurrence.
19. Ongoing verification of direct observations of monitoring activities, corrective actio s, and direct measurement of the CCP's were not performed at the monitoring location. The HACCP plan was not validat d. *Repeat deficiency from last audit.*
20. Corrective action written in HACCP plan for monitoring and ongoing plant verifica ion did not meet FSIS 417.2(c)(7), 417.3(a)(2) 417.5(a)(3) regulatory requirements. *Repeat deficiency from last audit.*
22. The records were not maintained for corrective and preventive actions taken in resp nse to a deviation of CL's. Records keeping did not meet FSIS 417.5 regulatory requirements adequately. *Repeat deficienc from last audit.*
38/56. There was no door between dry storage room and mechanical work shop to prev nt the entrance of rodents and other vermin. Establishment officials ordered correction. Council Directive 64/433 Annex 1 Chapter 1(v) was not met.
45/56. a) Numerous combo bins were cracked and deteriorated in the hog heads cooler room. Establishment officials ordered correction. . Council Directive 64/433 Annex 1 Chapter 1(w) was not met.
b) A few sanitizing facilities for knives in the slaughter room were designed in such a way that it was not possible to sanitize knife completely and effectively. Establishment officials ordered correction. . Council Directive 64/433 Annex 1 Chapter 1(q) was not met.
c) Containers for inedible (pet food) and edible product were not identified to prevent cross utilization and to prevent the adulteration of product. . Council Directive 64/433 Annex 1 Chapter 111. 4 was not m t.
d) Water was leaking through ceilings in the boning room. There was no product unc rneath. Establishment officials ordered correction. . Council Directive 64/433 Annex 1 Chapter 111. 3 was not met.
e) There was no facility for retained viscera and offal for veterinary postmortem disp sition at the carcass and viscera inspection station. Establishment officials ordered correction. . Council Directive 64/4 33 Annex 1 Chapter1(j) was not met.
51. Veterinary meat inspector did not meet 417.8 regulatory requirements such as revi wing the CCP records; reviewing and determining the adequacy of corrective actions taken when a deviation occurred; direct observation or measurement at a CCP; on-site observation and record review. *Repeat deficiency from last audit.*
b) Meat inspection officials most of the time were not identifying the pre-operational and operational sanitation deficiencies and any corrective actions taken were not documented. *Repeat deficiency from las audit.*
57. Monthly supervisory audits were conducted since January, 2002. These audits did not reflect the conditions of the establishment. *Repeat deficiency from last audit.*
58. Establishment 193 was evaluated as acceptable/re-review during last audit on 10/0)/01. Because of noncompliance with implementation of SSOP, HACCP regulatory requirements, Council Directive 64/433 EEC, and lack of enforcement requirements by GON inspection officials, the status of this establishment is not equiv lent to that required in the U.S. program. All the above deficiencies were discussed with Dr. Ron Dwinger, Staff Offi er, and he agreed to remove Establishment 193 from the list of establishments eligible to export meat and meat pro lucts to the United States, effective June 12, 2002. **Establishment # 193** **Audit date 06/12/02**

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	6/12/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hendrix Meat Group C.V. Druten	06/07/02	236	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faiz R. Choudry		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag	
43. Water Supply	
44. Dressing Rooms/Lav tories	
45. Equipment and Uten ils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov rage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identificatior	
54. Ante Mortem Inspec ion	
55. Post Mortem Inspec ion	
Part G - Other R gulatory Oversight Requirements	
56. European Communi Directives	X
57. Monthly Review	
58. Intended En orcement Actions	X
59.	

60. Observation of the Establishment

12. a) Automatic carcass splitting saw was not completely washed/sanitized as required in the slaughter room. Establishment officials ordered correction.
b) Hog carcasses were contacting employee's boots at the final carcass trimming station in the slaughter room. Establishment officials ordered correction.

18. Monitoring of CCP was not performed as described in the procedures such as CCP was identified at the bung dropping and evisceration stations but monitored after carcass splitting by trimmers. FSIS 417.2 c)(4) regulatory requirements was not adequately met. *Repeat deficiency from last audit.*

19. Ongoing verification of direct observations of monitoring activities, corrective actions, and direct measurement of the CCP's was not performed at the CCP's monitoring location. The HACCP plan was not validated. FSIS 417.2(c)(7) and 417.5(c) was not adequately met. *Repeat deficiency from last audit.*

20. The HACCP plan called for ongoing verification of CCP for zero tolerance for fecal contamination 100 carcasses twice daily. Corrective actions stated did not meet FSIS 417.3 regulatory requirements when deviations occurred. *Repeat deficiency from last audit.*

22. The records were not maintained for monitoring CCP's for zero tolerance for fecal materials and corrective and preventive actions taken in response to a deviation of CL's. FSIS 417.5 regulatory requirements was not adequately met. *Repeat deficiency from last audit*

38/56 A build-up of dust or debris and cobwebs was observed in the dry storage room and packaging some materials were not stored on racks or racks were not high enough to monitor pest control and sanitation programs. Numerous items such as pipes, old machines and other equipment were stored in the dry storage room. Numerous holes through the walls to outside and gaps at the bottoms of door in the dry storage room were not sealed properly to prevent the entry of rodents and other vermin. Council Directive 64/433 Annex 1 Chapter 1(v) was not met.

46/56. a) There was no protection to prevent contamination from employee's boots over automatic viscera conveyor belt at the evisceration station in the slaughter room. Establishment officials ordered correction. Council Directive 64/433 Annex 1 Chapter 111.3 was not met.
b) Insulation over ducts was wet and beaded condensation was observed, potential for drip contamination or adulteration of product in carcass cooler. Establishment officials ordered correction. Establishment officials ordered correction. Council Directive 64/433 Annex 1 Chapter 111.3(c) was not met.

51. Veterinary meat inspector did not meet 417.8 regulatory requirements such as reviewing the CCP records, reviewing and determining the adequacy of corrective actions taken when a deviation occurred, direct observation or measurement at a CCP, and on-site observation and record review. *Repeat deficiency from last audit.*

58. GON inspection officials indicated that establishment would be given 30 days notification of intended enforcement actions related to HACCP system inadequacy determinations on June 7, 2002.

Establishment # 236 Audit date 06/07/02

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	6/7/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Boom Fine Food Manufacturers B.V. Putten	06/17/02	242	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faiz R. Choudry		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	X
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag	
43. Water Supply	
44. Dressing Rooms/Lav tories	
45. Equipment and Utens ls	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov rage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspec on	O
55. Post Mortem Inspec ion	O
Part G - Other Regulatory Oversight Requirements	
56. European Communit Directives	
57. Monthly Review	X
58. Unacceptabl	X
59.	

60. Observation of the Establishment

9. The SSOPs procedures was not dated and signed by the person with overall on-site authority.

11. Establishment officials were not routinely evaluating the effectiveness of the Sanitation SOP's to prevent direct product contamination or adulteration of product.

15. a) The HACCP plan did not adequately conduct a hazard analysis and did not include all food safety hazards likely to occur. *Repeat deficiency from last audit.*
b) The HACCP plan did not list the procedures, and the frequency with which those procedures would be performed, that would be used to monitor each of the critical control points to ensure compliance with the critical limits. *Repeat deficiency from last audit.*
c) The HACCP plan did not list the verification procedures, and the frequency with which those procedures would be performed, that the establishment would use in accordance with 417.4. *Repeat deficiency from last audit.*
d) The HACCP plan did not meet FSIS 417.3 (3) regulatory requirements such as in response to a deviation from a critical limit measures to prevent recurrence are not established. *Repeat deficiency from last audit.*

18. Monitoring procedures identified in the HACCP plan were not adequately performed such as CCP's were not identified in the monitoring records. *Repeat deficiency from last audit.*

19. Ongoing verification such as direct observations of monitoring activities, corrective actions, direct measurement at a CCP, and the calibration of processing-monitoring instruments were not met adequate y FSIS 417.2(c)7, 417.4(a)(2) regulatory requirements. *Repeat deficiency from last audit.*

22. Records documenting the monitoring of CCP's and their critical limits was not including the recording of actual times. FSIS 417.5(a)(3) regulatory requirements was not adequately met. *Repeat deficiency from last audit.*

51. a) GON inspection officials were not verifying the adequacy and effectiveness of daily pre-operational and operational sanitation. Pre-operational sanitation was monitored one time on January 17, 2002 so far this year. *Repeat deficiency from last audit.*
b) Veterinary meat inspector did not meet 417.8 regulatory requirements such as reviewing the CCP records, reviewing and determining the adequacy of corrective actions taken when a deviation occurred, direct observation or measurement at a CCP, and on-site observation and record review. *Repeat deficiency from last audit.*

57. Monthly supervisory one audit was conducted by June 17, 2002.

58. Establishment 242 was evaluated as acceptable/re-review during last audit on 10 11/01. Because of noncompliance with implementation of SSOP, HACCP regulatory requirements and lack of enforcement requirements by GON inspection officials, the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with Dr. Ron Dwinger, staff officer, and he agreed to remove Establishment 242 from the list of establishments eligible to export meat and meat products to the United States, effective June 17, 2002.

Establishment # 242 Dated 06/17/02

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	Faiz R Choudry 6/17/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sturko Meat Apeldoorn B. V. Apeldoorn	06/14/02	312	Netherlands
	5. NAME OF AUDITOR(S) Dr. Faiz R. Choudry		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground[illegible] and Pest Control	X
39. Establishment Constr[illegible]iction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag[illegible]	
43. Water Supply	
44. Dressing Rooms/Lav[illegible]itories	
45. Equipment and Uten[illegible]ils	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov[illegible]erage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identificatio[illegible]	
54. Ante Mortem Inspec[illegible]ion	
55. Post Mortem Inspec[illegible]tion	
Part G - Other Regulatory Oversight Requirements	
56. European Commun[illegible]y Directives	X
57. Monthly Review	
58. Intended En[illegible]orcement Actions	X
59.	

60. Observation of the Establishment

11. Establishment officials were not routinely evaluating the effectiveness of the Sanit tion SOP's and the procedures therein in preventing direct contamination or adulteration of product.

12/56. a) Automatic carcass splitting saw was not completely washed/sanitized as requi ed in the slaughter room. Establishment officials ordered correction. CD 64/433/ECC. Chapter 111 3(c)
b) Dirty water droplets from overhead walkway over the automatic viscera conveyor w ere falling onto edible viscera. Establishment officials ordered correction.

13. The daily pre-operational and operational sanitation deficiencies most of the time were not identified and any corrective action taken were not documented by the establishment officials

19. Ongoing verification of direct observations of monitoring activities or measureme t of at a CCP and the review of records did not meet FSIS 417.2(c)(7), 417.4(a)(2) regulatory requirements adequately The HACCP plan was not validated.

20. Corrective and preventive actions written in HACCP plan for monitoring and ong ing plant verification did not meet FSIS 417. 3(a)(2) and 417.5(a) (3) regulatory requirements adequately.

22. The records were not maintained at the identified critical control point for monito ng CCP's for zero tolerance for fecal materials. The entries were not made at the time when deviation occurred, including t e time and signature/initials by the responsible establishment employee. FSIS 417.5 regulatory requirements was not ade uately met.

38/56. A build-up of dust or debris was observed in the dry storage room and packagi g materials were not stored on racks or racks were not high enough to monitor pest control and sanitation programs. Counc l Directive 64/433 EEC Annex 1 Chapter 1(v) was not met.

45/56. a) Automatic head conveyor and edible product conveyor belts were deteriora ed and with broken paddles in the cut-up room. Council Directive 64/433 EEC Annex 1 Chapter 111, 3(c) was not met.
b) Containers for edible and inedible product were not identified to prevent cross utili zation and to prevent cross contamination or adulteration of product in the boning room. Council Directive 64/43 EEC Annex 1 Chapter 111.4 was not met.
c) There was no facility to retain viscera and offal with the carcass for veterinary po t mortem disposition in the slaughter room. Council Directive 64/433 EEC Annex 1 Chapter 1.(j) was not met.

46/56. Beaded condensation was observed on overhead air soaks and ducts in the sla ghter room. Establishment officials ordered correction. Council Directive 64/433 EEC Annex 1 Chapter 111, 3(c) was no met.

51. a) Veterinary meat inspector did not meet 417.8 regulatory requirements such as eviewing the CCP records; reviewing and determining the adequacy of corrective actions taken when a deviation occurred; lirect observation or measurement at a CCP; on-site observation and record review.
b) Meat inspection officials most of the time were not identifying the pre-operation l and operational sanitation deficiencies and any corrective actions taken were not documented.

58. GON inspection officials indicated that establishment would be given 30 days nc ification of intended enforcement actions related to HACCP system inadequacy determinations on June 14, 2002.

Establishment # 312 **Audit date 06/14/02**

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	Faiz R. Choudry 6/14/02

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checkli ;t

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dumeco Helmond B. V. Helmond	06/06/02	378	Netherlands
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faiz R. Choudry		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requiremer ts. Use O if not applicable.

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	O
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

P: rt D - Continued Ec nomic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Ground and Pest Control	
39. Establishment Constr ction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewag	X
43. Water Supply	
44. Dressing Rooms/Lav tories	
45. Equipment and Uten ls	X
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	X
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Cov rage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspec ion	
55. Post Mortem Inspec ion	
Part G - Other R gulatory Oversight Requirements	
56. European Communi Directives	X
57. Monthly Review	X
58. "Equal to " s tatus	X
59.	

60. Observation of the Establishment

11. Establishment officials were not routinely evaluating the effectiveness of the Sanit ıtion SOP's to prevent direct product contamination or adulteration of product.
12. a) Dried pieces of meat and fat were observed in numerous combo bins for edible product and dead insects in one combo bin. A few trees for hanging hams were found with grease. Neither establishm nt nor GON inspection officials took corrective action. *Repeat deficiency from last audit.*
b) Dripping condensate, from overhead refrigeration units, beams, and ducts that was ıot cleaned/sanitized daily, was falling onto hog carcasses, hams, and offal in the coolers and shipping room. Neither establisl ment nor GON inspection officials took action.
c) Several employee's were not using hygienic work habits to prevent direct product c ıntamination such as: Employee's were observed handling unclean equipment, picking up pieces of meat from the floor, ıandling dropped ham for reconditioning and, without washing hands handled edible product; An other employe picked up meat scraper from the floor and, without washing hands and washing/sanitizing meat scraper handled edible prodı ct in the boning room. *Repeat deficiency from last audit.*
d) Hog carcasses were contacting work platform and employee's boots at the carcass t ımming stations. *Repeat deficiency from last audit.*
13. The daily pre-operational and operational sanitation deficiencies were not identifi d and any corrective action taken were not documented by the establishment officials. *Repeat deficiency from last audit.*
19. Ongoing verification of direct observations of monitoring activities, corrective ac ions, direct measurement of the CCP's was not performed at the CCP's monitoring location. The HACCP plan was not valid: ted. FSIS 417.2(c)(7) and 417.4 (a) (2) regulatory requirements was not adequately met. *Repeat deficiency from last audit.*
20. The HACCP plan called for ongoing verification of CCP's for zero tolerance for ecal contamination 100 carcasses twice daily and in case of deviation, another set of samples will be verified within an hour. Corrective actions stated did not meet FSIS 417.3 regulatory requirements when deviations occurred on June 3, 4, and 5, 20 2. *Repeat deficiency from last audit.*
22. The records were not maintained for monitoring CCP's for zero tolerance for feca materials and corrective and preventive actions taken in response to a deviation of CL's did not adequately meet F SIS 417.5 regulatory requirements. *Repeat deficiency from last audit.*
42. Excessive water pooled on the floor due to poor drainage system, potential for sp ashing of dirty water from the floor onto cleaned edible product containers and employees' clothes in the equipment wasl ing room. Council Directive 64/433 Annex 1 Chapter 1 . 1(r) was not met.
45/56. a) Numerous combo bins for edible product ready for use, were cracked and adly deteriorated in the storage room. . Council Directive 64/433EEC Annex 1 Chapter 111.3(c) was not met.
b) Containers for edible and inedible product were not identified to prevent cross u lization and to prevent contamination of product in the boning room. Council Directive 64/433/EEC. Anne 1 Chapter III. 4 was not met. *Repeat deficiency from last audit.*
46/56. a) Dripping condensate, from overhead refrigeration unit that was not cleane 'sanitized daily, was falling in the product weighing room. There was no product stored directly underneath. Council Directive 64/433/EEC. Chapter III. 3(c)
b) An employee crossed over unprotected edible product conveyor belt, potential fo cross contamination of product. . Council Directive 64/433/EEC. Chapter III. 3. was not met. *Repeat deficiency from ast audit.*
48. Containers for edible and inedible product were not identified. *Repeat deficienc from last audit.*
51. a) Veterinary meat inspector did not meet 417.8 regulatory requirements such as reviewing the CCP records, reviewing and determining the adequacy of corrective actions taken when a deviation occurred direct observation or measurement at a CCP, on-site observation and record review. *Repeat deficiency from last audit.*
b) Meat inspection officials most of the time were not identifying the pre-operatior al and operational sanitation deficiencies and any corrective actions taken were not documented. *Repeat deficiency from last udit.*
57. Monthly supervisory two audits were conducted since December, 2001. *Repeat deficiency from last audit.*
58. Establishment 378 was evaluated as acceptable/re-review during last audit on 1 /12/02. Because of noncompliance with implementation of SSOP, HACCP regulatory requirements, Council Directive 64/4 3/EEC, and lack of enforcement requirements by GON inspection officials, the status of this establishment is not equ valent to that required in the U.S. program. All the above deficiencies were discussed with Dr. Ron Dwinger, Staff O ficer, and he agreed to remove Establishment 378 from the list of establishments eligible to export meat and meat p oducts to the United States, effective June 6, 2002.

Establishment 378 **Audit date 06/06/02**

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faiz R. Choudry	Faiz R Choudry 6/6/02

Attachment G

Ministerie van Landbouw, Natuurbeheer en Visserij

Ministry of Agriculture, Nature Management and Fisheries

United States Department of Agriculture
Food Safety and Inspection Service
Dr. John C. Prucha
Policy, Program Dev. and Evaluation
Washington D.C. 20250
USA

landbouw, natuurbeheer en visserij

Your letter of	your reference	our reference	date
27-8-2002		VVA02.3340/FIV	25-10-2002
re:		extension no.	enclosures
response to draft report audit 2002		+31-70-3785036	1

Dear Mr Prucha,

Below you will find the Netherlands' reaction to the draft audit report on the Dutch meat inspection system, performed by the FSIS from 5 June through 1 July 2002. A copy of this letter will also be sent to the European Commission.

The Netherlands attaches great importance to the export of animal products to the United States. Dutch companies are keen to compete on the American market, in the understanding that opportunities are equal for all parties. We accept that the United States sets conditions for the safety of imported products – and that third countries' compliance with these is checked by the FSIS – as similar policy applies in the Netherlands and the EU. On behalf of the Netherlands, I would like to reassure you of our commitment to the United States' standards for safety in meat and meat products from the Netherlands, pursuant to the agreement between the European Union and the United States.[1]

The Netherlands takes the points mentioned in your letter seriously. Below, I explain which measures have been or will be taken to resolve these points. However, I also would like to comment on certain elements of the draft report that could be improved and these are also brought up, below.

General remarks

1. The negative general conclusion on page 1 of the accompanying letter ("... a two-year trend of gradually deteriorating conditions") deserves to be qualified. The trend observed by the FSIS has started with the arrival of a new auditor (in the 2001 audit), whose method of assessment differs strongly from that of the auditor who previously visited the Netherlands. Not only did the new auditor include certain new aspects in his evaluation, he also judged shortcomings more harshly.

[1] Agreement between the European Union and the United States on sanitary measures to protect public and animal health in the trade in live animals and animal products, June 5 2002.

Ministry of Agriculture, Nature Management and Fisheries
Food and Veterinary Affairs
Bezuidenhoutseweg 73
Postal Address: 20401
2500 EK Den Haag
Telephone: 070-3785131
Fax: 070-3786141
Telegramme Address: Landvis
Web: www.minlnv.nl

Following the 2001 audit, both the National Inspection Service for Livestock and Meat (RVV) and Dutch slaughterhouses made every effort to follow up the recommendations and critical remarks of the 2001 audit report, in order to meet the more stringent conditions. In this, they were partly successful, because of the 12 establishments inspected in the 2002 audit, four were found satisfactory, while in 2001 *all eight* establishments visited had been found not acceptable. Taking into account the more stringent execution of the audit, the relatively short period between the audits of 2001 and 2002 and the fact that four establishments have already been approved compared to none in the year before, I feel that your conclusion is far too negative.

In this respect, please recollect my first comments on the draft report of the 2001 audit by the FSIS. Then, too, I objected to the general air of negativity, and the fact that the audit had been conducted much more strictly than had been done by the previous auditor. In restate the comment I made to the 2001 audit that to my opinion, uniformity in auditors' assessments would be most desirable.

2. In the draft report, shortcomings are listed more than once, resulting in a longer list which makes the situation appear more negative than it actually is. For example, the remarks in point 12.5 ("six establishments did not fully comply with EC Directive 64/433"). These remarks have already been made earlier in the text. Item 38 is a repeat of point 9, first bullet; item 39 is the same as the fifth bullet in point 9; item 42 is a repeat of point 9, sixth bullet; item 45 is equivalent to point 9, third bullet; item 46 is equivalent to point 9, second bullet; item 55 is a repeat of point 12.4.2. Where possible, repeated mention of shortcomings should be deleted from the final report.

3. Monthly review
Point 12.3 states: "in five establishments, supervisory reviews were not conducted on a monthly basis". According to the individual reports, however, the monthly reviews did take place (see point 57 of the audit checklists for establishments 64, 89, 129, 242 and 378). The number of monthly review visits varied from one to three. Already in response to the 2001 audit report, the Netherlands added a structural monthly review to its inspection order. (see my response to the 2001 audit report, (letter VVA02.926/JB, page 3 second bullet). This measure was implemented in spring 2002 and as a result of this, the number of monthly reviews realised was still low during the 2002 audit. Since then, the reviews take place as required.

During the teleconference on 1 May 2002 between the Ministry and RVV for the Netherlands and the FSIS and IPS for the United States, the Netherlands has stressed the fact that the time to prepare the implementation of the new improvements was very short (from publication of the 2001 audit report in April 2002 to the audit in June 2002). This short preparation time explains the relatively small number of monthly reviews.
The American participants in this teleconference assured us that the auditor would keep this fact in mind.
It is apparent from the draft audit report that he did not, nor did he take into account that the number of monthly reviews simply could not have been greater in consideration of the time at which RVV started these in 2002.

The report should be amended on this point, and where this comment affects the general conclusions relating to the degree of official supervision of the establishments.

4. The Netherlands is aware that the FSIS has also become more stringent in its inspections of establishments in the United States. It would appear, however, that American establishments have had more time to adjust to this more stringent policy than establishments in the Netherlands.

Remarks concerning parts of the report

1. Uniform implementation of rules and requirements (page 7, point 6.2, first paragraph). A uniform implementation is ensured by:
   - adapting and improving work orders which can be accessed by all RVV employees via the RVV-intranet;
   - regular staff meetings for all RVV employees charged with supervision of US recognised establishments.

2. Pages 9 and 10; point 6.3 second and third paragraphs. The reports says that there is "very little direct supervision by Central or Regional Directors" or "over the shoulder supervision above team level". I would like to explain how supervision is organised at RVV:
   - monthly checks by the head of the inspection team;
   - audits of US recognised establishments are carried out every six months by specially trained auditors;
   - routine business inspections are held every month at meat product establishments;
   - a hygiene report is made every month at slaughterhouses and cutting plants. The Quality management division reviews the situation at US recognised establishments once a year and makes recommendations for improvement at that time.

   There is a clear supervisory structure: the acting veterinarian is responsible for the day-to-day activities of the establishment, the teamleader conducts monthly checks and the RVV head office (quality management) is responsible for the highest level of supervision. Pursuant to the audit report, the monthly checks by the team head will be elaborated.

3. Number of specialists per district (page 11, point 5.5, third paragraph): every district has four specialists (red meat, poultry meat, live animals, and animal products) and one quality officer. Please include the quality officer in the report.

4. Section 10, p. 15: In the second paragraph, foot-and-mouth disease (FMD) is referred to as a serious public health risk. I strongly disagree with this. It is common knowledge that FMD poses no risk whatsoever to public health. Please delete this passage from the report.

5. HACCP implementation (page 16; point 11.1, th rd paragraph): It is not clear in the text how this point differs with the shortcomings na med after the first bullet ("four establishments did not adequately monitor the established CCPs") and after the fifth bullet ("six establishments did not adequately r ionitor the established CCPs"). Please clarify the differences between the two : hortcomings, or delete one of them if the points are referring to the same observed s iortcoming.

Measures taken:

1. All establishments which were "marginally acce ptable", were again visited within thirty days after the American auditors' inspecti on. One establishment voluntarily gave up its approval (Dumeco Den Bosch, EC numbe 89). The inspection reports for the remaining four establishments have already be n sent to Washington, but are also attached to this letter (appendixes I to IV). All fc ur establishments have corrected the observed shortcomings and have therefore bee approved by the RVV for export to the USA.

2. Laboratory audits (page 13)
   - Proficiency test for chloramphenicol by RIKILT: this test took place in July 2002 (FAPAS)
   - Programme to test *Listeria monocytogenes*: The LRVV Central Laboratory has developed a programme to test ready-to-ea products for *Listeria m.* four times per year. The programme will be implemented i s soon as possible.

3. Verification by a supervisor
   The team leader will visit US recognised establis ments on a monthly basis. Various aspects, decided differently for each visit, are th en checked. These include:
   - supervision to veterinarian in charge;
   - a check of the establishment's SSOP, in particular corrective and preventive measures;
   - verification of the CCPs;
   - implementation of improvements recor mended by the audit team;
   - scrutiny of the records of the veterinaria n in charge, a comparison with the establishment's records and if necessary dis uss points for improvements.

   The RVV Head Office has designed a verification form to be used for these monthly reviews.

4. As one of the results of the findings of the Amer can audit team, the audit frequency at Dutch US recognised establishments will be ir creased. Over the next few months, all fifteen establishments will be subjected to int erim audits to be conducted by a three-man audit team (one of whom shall come from the RVV Head Office). The audit team will look closely at how the shortcomings recorded in the FSIS audit report have been dealt with. Establishments which fail to me et the United States' requirements will be struck off RVV's list of establishments approv d for export to the USA.

5. RVV employee training

- In November 2002, RVV employees will be following a course designed especially for them and taught by an American instructor.
- A meeting will be held with the responsible veterinarians, heads of team and meat inspectors to analyse the activities that take place at a US recognised establishment and the shortcomings cited in the FSIS report. This should enhance the uniformity and supervision of these establishments.
- At least two RVV officers will follow a HACCP training course in the United States.

I trust that this letter is sufficiently clear about the errors found in the draft FSIS report and the measures that the Netherlands has taken to remedy the shortcomings observed by the audit team. I hope that all inaccuracies will be resolved in the final report, and that this letter will be annexed to that report.

Yours sincerely,

Frits Pluimers

Chief Veterinary Officer

AUDIT HMG Druten
CORRECTIVE MEASURES

Date:	05 July 2002
Members of the audit team:	A. van Sambeek, official veterinarian HMG Druten R. Dwinger, RVV head office M. Kroeze, RVV District North K. Hellwig, RVV District East
Supervisor auditee:	W. Stoolk, Head Q&A HMG Druten J. de Jong, Office Manager HMG Druter
Cc to:	Director RVV District East HACCP dossier audit leader Head Wychen district Team Manager Druten Manager audit team
Relevant regulations:	64/433/EEC on health problems affecting intra-Community trade in fresh meat *Besluit productie en handel in vers vlee* GMP manual (version 2001) HACCP manual (part III: slaughterhouse and cutting plant) FSIS Directive 12.17.98 RVV slaughterhouse and cutting plant : tandard sheet 13-04-99
Presented for audit:	The Quality Handbook of HMG Druten Production plant (Approval no EEC 236) as lastly amended 02 July 2002 with references made to the plant's inspection and registration forms, results of microbiological tests of carcasses and meat cuts, cleaning and disinfection protocols, pest control plan etc.

The audit (30 days after the US inspection) did not address all the issues brought forward by Mr Choudry on 7 June 2002.

VERITAS will carry out a validation before 15 July 2002

Buildings and layout

LRM is packaged and clearly marked throughout the production process and stored separately.
Pipes in cell 2 have been insulated. Condensation no longer occurs.
The Dolav bins in use are all in order.
Packaging is fully cleansed, inspections intensified. Where irregularities are found the packaging is marked and returned to go through the cleaning process once more.
The rolling door in the washing facilities has been adjusted; it no longer touches the floor.
The final trimming area has been adjusted as required.
The HACCP protocol has been adjusted.
Pre-operational and operational sanitation protocols are followed closely and reported. They are also carried out at the start of the second shift.
Random carcass sampling is based on tables in Geigy scientific 7th edition.

Monitoring and verification of CCP faecal contamination

The faecal contamination monitoring process is described in great detail in the manual and complied with by all the workers at the plant. Control and registration forms are completed and kept up-to-date and meet all US requirements.
A separate inspection officer monitors faecal contamination (between carcass splitting machine and the veterinary inspection area at light intensity >540 lux). Verification of monitored carcasses (50) takes place once a day in the same monitoring area by a quality control officer. When no non-compliance is found all

carcasses processed that day are inspected the next day at the cutting plant where any contamination found is recorded and washed off.
Production workers are trained by slaughterhouse staff officers to keep the risk of contamination to a minimum.

Monitoring and verification of CCP carcass and organ temperatures

Carcass and organ temperatures are controlled before consignments are shipped via the dispatch area. Before each consignment leaves the premises five random inspections are carried out and recorded. When non-compliance is found the meat (carcasses and cuts) is returned to cold store and documented. Climate control is based on the Wiscon climate control programme. The data logger automatically reads temperature developments in the carcasses and temperatures are taken and recorded manually every day in the cold store before carcasses are cut up.
The thermometer is callibrated once a month.
Checklists are completed stating frequency of controls, corrective measures on non-compliance, preventive measures and verification protocols.
Documents are shown on demand.
The temperatures of the meat during transport is a point of concern (CP)
Columns for monitoring and verification have been added to the CCP matrix and flow charts have been adapted accordingly.

RVV activities with respect to US approved production plants.

The RVV requirements for the US approved establishment in Druten are laid down in procedures and work instructions. Verification of CCP 1 is carled out and recorded daily at 12 00 hrs and at the end of the slaughtering day.
Every month the team leader or another supervisor checks the production process controls (controlling the control points).
The local RVV officers daily verify standards (CCP enforcement).
Verification involves direct measurements, direct observation and checklist controls.
All activities are laid down in procedures and protocols and can be traced.
All non-conformities were remedied to comply with FSIS Directive 12.17.98, the RVV slaughterhouse and cutting plant standard sheet 13-04-99 and the sanitation plan. Registration and sanitation forms are completed daily and checked by the management.
The PBS handbook meets national and US requirements.

Summary:
On 05 June 2002 (30 days after the US inspection) an audit took place at HMG Druten to see whether corrective measures were in place to correct non-conformities pointed out by Mr Choudry on 7 June 2002.
All non-conformities (found in the quality handbook and on the shop floor) were remedied. The firm now meets the RVV standards for US approved establishmens.
The production process management system covers the entire process from the reception of slaughter pigs up to the end product (carcasses, meat cuts, slaughter by-products, LRM, SRM)

Conclusions
The production process management system at HMG Druten fully complies with the RVV requirements for US approved establishments. This includes the establishment's documentation, standards laid down, corrective measures for non-conformities, inspection methods and frequencies etc.
The audit team therefore advises the RVV to issue a US approval to HMG Druten.

This report was drawn up by Dr K. Hellwig, leader of the audit team.

CORRECTIVE MEASURES
AUDIT DUMECO APELDOORN

Date:	16 July 2002
Members of the audit team:	G. Vernooij, official veterinarian Dumec Apeldoorn N. Verweij, RVV District East M. Kroeze, RVV District North K. Hellwig , RVV District East J. Schiewe, RVV team leader Apeldoorn B. de Roos, RVV inspection officer Apeld oorn S. Nieuwendijk, designated member of F VV team Apeldoorn
Supervisor auditee	R. Helders, quality officer Dumeco Apelc oorn C. v.d. Linden, quality officer Dumeco Ap eldoorn J. Hogeboom, quality officer Dumeco Co ncern G. Rouwgoor, production manager Dum eco Apeldoorn
Cc to:	Director RVV District East HACCP dossier audit leader Head Apeldoorn district Team Manager Apeldoorn Members of the audit team
Relevant regulations:	64/433/EEC on health problems affectin intra-Community trade in fresh meat *Besluit productie en handel in vers vlees* GMP manual (version 2001) HACCP manual (part III: slaughterhouse nd cutting plant) FSIS Directive 12.17.98 RVV slaughterhouse and cutting plant st ndard sheet 13-04-99
Presented for audit:	The Quality Handbook of Dumeco Apeld oorn Production plant (Approval no EEC 312) as lastly amended 10 July 2002 with references made to the plant's inspectio and registration forms, results of microbiological tests of carcas es and meat cuts, cleaning and disinfecting protocols, pest control p lan etc.

During the present audit (30 days after the US inspection) those subjects were checked that were found to be deficient during the visit by dr Choudry and dr. Moughal on 14 June 200 2.

Lloyd's will validate the HACCP plan before 15 August 2002

Buildings and layout

- Slaughter room

- Employees are no longer crossing unprotected edible product conve or belts at the evisceration station. There is no longer a danger of contamination by dripping con lensate;
- Air curtains in the slaughter room were replaced immediately after ir spection and are checked and replaced at regular intervals;
- Corrective action was taken to ensure that the 2 carcass splitters mee sanitary requirements. Disinfecting and sanitation procedures are in place to keep the rollers lean.
- Corrective action was taken to ensure that the fans in the clean slaug ter area work properly. The white plastic parts have been replaced by stainless steel.
- The temperature of the sterilisers in the slaughter room are checked nd recorded by the plant before and during operations. They are monitored by local RVV inspec ors.
- At the inspection station a facility has been put in place for the temp rary storage of problem carcasses and parts for inspection by the official veterinarian.

➢ Cutting room

- Corrective action was taken directly after inspection to ensure that the pigs' heads conveyor belt meets the requirements.
- the storage room for packaging in the cutting room has been seen to. The materials are now stored in keeping with sanitary requirements.

➢ Documentation

The HACCP manual gives a full and detailed decription of CCPs [item, critical limits and tolerances, monitoring frequencies, monitoring methods, registration of the records, the responsible authority, verification and actions taken when deficiencies are found].

- The monitoring and verification of CCP –1 [faecal contamination] takes place after the carcasses are split. The light intensity in this area [pre–inspection] is ≥ 540 lux.
- The monitoring and verification of CCP –1 as documented in the Quality Handbook corresponds with the actual situation in the slaughter area.

- The monitoring and verification of CCP –2 [temperature control of carcasses and meat cuts ≤ 7° C and organs ≤ 3° C].
- The CCP lies before shipping in the shipping room.
- Each shipment's temperature is checked at least 5 times. If there is any period where temperature exceeds the control limits corrective action is taken immediately. The CCP 2 protocol is described in work instructions and is part of the CCP matrix.
Automatic Temperature Recorders monitor temperatures in cold stores and are checked at regular intervals.
Temperatures are taken and recorded manually every day in the cold store before carcasses are cut up.
The thermometers are calibrated once a month for accuracy.
The shipment of partly chilled meat is a CP.

➢ matrix CCPs

The matrix of the CCPs was corrected by the plant immediately after inspection.
A verification column was added to the matrix.
Flowcharts have also been drawn up to meet US standards.

➢ Pre-operational sanitation en operational sanitation

- Pre-operational and operational sanitation inspections are carried out daily by the plant. The results are recorded fully in monitoring and registration forms. Where deficiencies are identified corrective action is taken immediately. The time it takes to remedy deficiencies is documented as well. All monitoring forms are checked and signed by the head of the quality department.
Sanitary conditions in the plant are thus guaranteed.

➢ RVV activities with respect to US approved production plants

The RVV carries out pre-operational and operational sanitation inspections daily. The results obtained by the RVV and the plant itself are compared and where deficiencies are identified corrective action is taken immediately.
RVV requirements are laid down in procedures.
RVV inspection officers verify the adequacy and effectiveness of CCPs daily.
Verification consists of three parts: direct measurement, direct observation and a verification of checklists.

All activities are laid down in procedures and protocols and can be t aced.
Zero tolerance for faecal contamination: 11 carcasses are checked or faecal contamination in the inspection area every day. Records can be verified. The company will be notified (for non-compliance), whenever a carcass positive for faecal contamination is detected.
Every month the team leader or another supervisor checks the prod ction process controls (controlling the control points). All this is documented.

All deficiencies have been corrected to meet the requirements laid d wn in RVV slaughterhouse and cutting plant standard sheet 13-04-99, the FSIS Directive 12.17.9 and the plant's sanitation plan. Findings are recorded daily on registration forms and checklist , which are verified by the management. The plant's HACCP plan complies with the national an l US requirements.

Summary:
On 16 July 2002 (30 days after the US inspection) an audit took place at Dum co Apeldoorn BV to see whether corrective measures were in place to correct the deficiencies obser ed by US auditors on 14 June 2002.
All deficiencies (found in the quality handbook and on the shop floor) were emedied. The plant now meets the RVV standards for US approved establishments.
The plant's HACCP plan covers the entire process from the reception of slaug ter pigs up to the end product (carcasses, meat cuts, slaughter by-products, LRM, SRM)

Conclusions
The HACCP plan at Dumeco Apeldoorn BV fully complies with the RVV requir ments for US approved establishments. This includes the establishment's documentation, standards aid down, corrective measures for deficiencies, inspection methods and frequencies etc.
The audit team therefore advises the RVV to issue a US approval to Dumeco A peldoorn BV.

This report was drawn up by the leader of the audit team,

Dr K. Hellwig

RVV Audit Report (following 30-day US audit)

Date of audit	30 July 2002	Establishment EEC approval no	DUMECO Weert BV 64
RVV officials	F. Scheerbaum (audit leader) K. Hellwig (Team member) J. Stevens (Inspector) P. Vergunst (Team member)	Type of establ.	EEC Pig slaughterer –A EEC Cutting plant -B
DUMECO staff	J. Scheffers (QM) H. Vlutters (Manager) J. Hoogeboom (QM)	Address	Oude Graaf 15 6002 NL Weert Tel 0495 582222 Fax 0495 543570 Email address: j.scheffers@dumeco.nl www.dumeco.nl
Relevant regulations:	64/433/EEC on health problems affecting intra-Community trade in fresh meat *Besluit productie en handel in vers vlees* GMP manual (version 2001) HACCP manual (part III: slaughterhouse and cutting plant) FSIS Directive 12.17.98 RVV slaughterhouse and cutting plant standard sheet 13-04-99		
Annexes	2 reports		

General

13 June 2002 was the final day of the US audit at DUMECO Weert BV. The establishment was evaluated as 'marginal'.
The inspector demanded that corrective actions be taken within 30 days to remedy the deficiencies found.
With respect to condensation the defiencies had to be remedied within one year.

The HACCP plan will be validated on 21 August 2002.

Audit of corrective actions (US auditor's remarks of 13 June 2002 are in italics)

Documentation

HACCP plan
CCP –1 [faecal contamination]
The monitoring of CCP –1 [faecal contamination] takes place after the carcasses are split (this is correct). Verification should take place at the same point and not later.
Corrective action has been taken to ensure that monitoring and verification take place at the same point.

CCP –2 [temperature control]
Two different temperature limits apply:

- *for carcasses and meat cuts the maximum temperature is 7° C*
- *for organs the maximum temperature is 3° C.*

Where two temperature limits apply there should be two CCPs.

In addition the temperature of the area is monitored.
The company is licensed to transport partly chilled meat (whic i is the third temperature limit to be monitored).
The number of CCPs should be 4 instaed of 3:

CCP 1	*faecal contamination*	*Zer) tolerance*
CCP 2	*Temperature limit organs*	*3° (*
CCP 3	*Temperature limit carcasses and meat cuts*	*7° (*
CCP 4	*Temperature limit partly chilled meat*	*29.. ° C*

Corrective action has been taken to ensure that CCPs are in pla ce for each temperature limit (see table). Whether the temperature limit of partly chille meat warrants a CCP will be reviewed by the company.

CCP survey
A CCP survey should summarise CCPs only and no CPs or oth er points of concern. A separate survey for CCPs should be drawn up.
CCPs should give a clear description of item, critical limits an ! tolerances, monitoring frequencies, monitoring methods, registration of th records, the responsible authority, verification and actions taken when defi iencies are found. References should be avoided.
Corrective action has been taken. A separate survey of CCPs h s been drawn up. The CCP matrix includes a column for verification.

R&D manual
The R&D plan outlining R&D procedures and instructions belc ngs in the R&D manual and not in the Quality manual
Corrective action has been taken and all R&D procedures and i structions are now incorporated in the R&D manual.
Checklists should give a clear description of 'dirt' to make it ea sier to find the cause.
Corrective action has been taken. Checklists in slaughterhouse nd cutting plant now clearly define the term.
During disinfecting and cleaning procedures the overseer chec s for compliance with the instructions (right concentration, water temperature, expos re time, washing down with drinking water after disinfecting etc). The results sh uld be recorded.
Corrective action has been taken. The overseer's findings are re orded on the checklist once a week.

HACCP analysis
The items to be checked must be described in greater detail.
Corrective action has been taken. The analysis is described in m ore detail.
For each CCP the potential physical, chemical and microbiologi al risks can now be determined with the help of a decision tree.

Preventive measures
The plant should do more to prevent risks.
Corrective action has been taken. In addition to the CCPs in pla e the plant is improving its work instructions to ensure more is done to prever t risks.

Verification of CCP 1
Where a significant rise in contaminated carcasses is observed monitoring and/or verification frequencies should be stepped up. (this can be done by increasing the number of carcasses to be monitored, e.g. 70 carcasses instead of the usual 50 or increasing inspection frequency e.g. every 30 mins. instead of every hour). Meanwhile the cause of the problem must be traced and, if necessary, corrections and/or new instructions put in place. Records must be made for verification.
Corrective action has been taken. The plant has opted for increasing inspection frequency. In such cases carcasses will be monitored every 30 mins. instead of every hour.
The checklists have been adapted accordingly.

The verification of CCP 1 should be incorporated in the HACCP plan.
Corrective action has been taken. The verification of CCP 1 has been incorporated in the HACCP plan.

Verification of CCP 2
CCP 2 can be verified but findings are not detailed enough.
Findings should include direct observation, checklist control and direct measurements.
Corrective action has been taken. The verification method for CCP 2 is now described in detail. Findings now itemise direct observation, checklist control and direct measurements (*HACCP Schaduwcontrole Dumeco Weert*)
Verification of CCP 2 points 3 and 4 should be included in the HACCP plan.
Corrective action has been taken. The verification of CCP 2 points 3 and 4 has been incorporated in the HACCP plan.

Checklist contamination of carcasses
The list should detail checks per carcass. For each carcass there should be two columns: one headed 'clean' and one headed 'contaminated'.
Corrective action has been taken. After each check the results are recorded in the columns 'number of contaminated carcasses' and 'number of clean carcasses'.

Checklist temperature control
Some checklists did not give dates or were not signed.
All checklists checked by the RVV provided the required date and signature.

Slaughter area
Cold store
Dripping condensate from
- *Insulated pipes*
- *Overhead conveyor system*
- *Roofing*

See report 2 (annex 2)

Cutting room
There is no leakage drain along entire length of overhead conveyor system. There is a risk of cross contamination (oil and condensate)

Corrective action has been taken. The entire length of the conveyor system has been provided with a leakage drain.

Plastic sheeting to protect electric equipment at carcass trimming station should be removed
Corrective action has been taken. The plastic sheeting has been removed.

Rusty railings in corner should be removed
Corrective action has been taken. The rusty railings have been removed.

Workers do not wash their hands in between handling pallets and handling meat crates
Corrective action has been taken. The workers have again been given instructions. This deficiency was not observed during the RVV audit.

Light at trimming tables is inadequate (min 540 lux)
Corrective action has been taken. A separate trimming table, which is adequately lighted for processing, has now been placed in cutting room.

At primal parts cut-up station the sanitising facility for the knives is too close to hand washing facilities, creating the potential for splashing of dirty water during hand washing.
Corrective action has been taken. The container with the sanitised knives has been moved to prevent contamination.

In one steriliser the water level is too low: the knives are not fully submerged. Equipment cannot be properly sterilised.
Corrective action has been taken. The lid has been adapted to allow knives to be fully submerged and thus properly sterilised.

Overhead beams over conveyor belts are dirty in places and should be cleaned more frequently.
Corrective action has been taken. Overhead beams have been cleaned. Inspection frequency will be stepped up and beams will be cleaned when necessary.

Cold store for carcasses
The plastic sheeting to protect electric equipment should be removed (rows 33 and 42)
Corrective action has been taken. The plastic sheeting has been removed.

Dripping condensate from
- *Insulated pipes*
- *Overhead conveyor system* not observed during RVV audit
- *Turning wheel cutting room 2nd chill room*

See report 2 (annex 2)

Cold store for pig's heads
The conveyor belt is damaged.
Corrective action has been taken. The conveyor belt has been replaced.

Dripping condensate at

- *First cutting station - pipes* Pipes will be insulated
- *Tonsil removal station* not observed during RVV audit
- *RVV inspection station* not observed during RVV audit

One worker was observed working with foot on viscera container.
The workers have again been given instructions. This deficiency was not observed during the RVV audit.

Container for organ hooks is dirty on the inside.
Corrective action has been taken. The container has been cleaned.

Steel and other utensils were found in the wash basin.
One steel was found in the wash basin. This was brought to the attention of the worker and immediately removed by the overseer.

Cold store for organs
In one place the insulation on the pipes is loose.
Corrective action has been taken. The insulation has been fixed.

RVV
Checklists
The system is too complicated. All relevant data should be put on one list: the items checked, the results of the checks, the corrective action taken when deficiencies are found, checks on corrective action, signature etc
Where deficiencies are found the next check (a max. 24 hrs later) must include a check of the corrections.
Deficiencies and corrections must be documented clearly (what action followed what deficiency, plus results etc)
Corrective action has been taken: checklists and procedures have been adapted to meet US requirements.

RVV inspections
Times of inspection must be recorded on checklists
Times of inspection are given on checklists. On some slaughter s mitation and cutting plant checklists inspection times have not been recorded.

Verification CCP 1
Although the RVV checks faecal contamination, it does not verify the plant's monitoring procedures. RVV verification should consist of

- *direct observation*
- *verification of checklists*
- *direct measurements*

CCP 1 is verified on the basis of the following document: Slaughterhall CCP 1 faecal contamination (instructions and registration).

Monthly RVV inspections
Reports are not detailed enough. A global check of all procedures is required.

Inspections by RVV inspectors of the plant's procedures and the work of the official veterinarian are described in more detail in new RVV instructions.

RVV Post-mortem inspection procedures
Lungs were checked adequately. Livers were not palpated as required but were simply lifted.
During the RVV audit the livers were palpated as required.

Agreements:
It was agreed that the plant would take the necessary steps to correct the deficiencies as laid down in the two reports (see annexes 1 and 2). In some cases deficiencies could be corrected by amending the plant's documents and implementing the new procdures.

Conclusion
The RVV audit team concludes that DUMECO Weert BV (EEC approval no 64) has implemented the corrective actions as ordered.

With the exception of the deficiencies described in the annexed reports DUMECO Weert BV (EEC approval no 64) now meets the RVV standards for US approved establishments.

The audit team recommends extending the establishment's US approval.

This report was drawn up by F.Scheerbaum, veterinary inspection officer, leader of the audit team, RVV district south
Date: 1 August 2002-08-13 City Helmond
Cc to

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Annex 1. RVV audit report 1 (p. 01 of 02)

RVV auditors K. Hellwig and F.Scheerbaum		Date 30 July 2002	
Auditee DUMECO Weert BV EEC 64		Cutting room and chill rooms	
contamination of carcasses			
Details of observed deficiency: In some places in the cutting room and chill rooms carcasses were observed to be contaminated with grease from overhead conveyors			
Confirmed by auditee Yes [X]/ No [ ]	Signature	Date: 30-07-2002	
In breach of: US and national requirements			
Corrective action: • Conveyor systems and chains will be sanitised regularly to prevent oil/grease from dripping onto carcasses. Sanitation procedures in place. • Ask supplier if chains can be greased in different manner. If so discuss alternatives, test for viability and implement possible alternative.			
Suggested by J. Scheffers		Correction in place by: 01-02-03	
Agreed by CM Yes [X]/ No [ ]	Audior F.Scheerbaum	Signature	Date: 30-07-2002

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RVV auditors K. Hellwig and F.Scheerbaum		Date 30 July 2002	
Auditee DUMECO Weert BV EEC 64		Throughout establishment	
Dripping condensate			
Details of observed deficiency: Condensate was observed in various places in the cutting room (under leakage drain) in the shipping area (on overhead conveyors) in the shipping area (chill room organs (crate room) chill room for carcasses (grey pipes)			
Confirmed by auditee Yes [X]/ No [ ]	Signature	Date: 30-07-2002	
In breach of: US and national requirements			
Corrective action: • Have specialised company in to study the issue and see if the problem can be reduced. • If so discuss alternatives, test for viability and implement possible alternative.			
Suggested by J. Scheffers		Correction in place by: 13-06-03	
Agreed by CM Yes [X]/ No [ ]	Audior F.Scheerbaum	Signature	Date: 30-07-2002

RVV audit report of corrective actions taken at Dumeco Scherpenzeel after US inspections of 20-6-2002.

Establishment:	Dumeco Scherpenzeel 82 EC 't Zwarte Land 13 3925 CK Scherpenzeel
RVV officials:	F.G.C. Harmsen, audit leader Dr. K. Hellwig, auditor US approved establishments B. de Roos, trainee N. Verweij, team leader O.Weikum, official veterinarian.
Dumeco staff:	F. van Hal, quality officer W. Hendriks, quality officer J. Hoogenboom, co-ordinator US approvals J. Klein Schiphorst, quality officer

The RVV has audited the corrective actions taken to remedy the 13 deficiencies identified by Dr. Ghias Mughal (USDA) on his inspection visit on 20 June 2002

1. Butcher's hook.
The butcher's hooks at the reception area are clean and hung at separate line marked with blue paint.

2. Red crates and Dolav bins.
The cleaning and disinfecting procedures for these items were found to be accurately described and in place. The procedures are verified regularly by RVV officials and recorded.

3. Condensation at slaughterline 3.
Steps were taken and no condensation was found on inspection tour of the company.

4. Frayed conveyor belts.
Frayed conveyor belts have been replaced or repaired. This is checked and recorded by RVV officials every day.

5. Cool store at end of reception line 4.
Ducts with deteriorated or broken insulation have been removed.

6. SSOPs.
SSOPs are described in detail in the HACCP manual and on checklists. The lists are verified by company staff and RVV officials and signed.

7. Description of deficiencies.
Company staff was given additional training. All deficiencies are described on forms.

8. Risk analysis
The risk analysis is clearly described and includes microbiological, chemical and physical risks, which are all put in a matrix. A verification column has also been added.